DIRECT EXAMINATION - JAMES F. GLENN

4789 STATE OF MINNESOTA 1 DISTRICT COURT SECOND JUDICIAL DISTRICT 2 COUNTY OF RAMSEY 3 _ _ _ _ _ _ _ _ _ The State of Minnesota, 4 by Hubert H. Humphrey, III, 5 its attorney general, 6 7 and 8 Blue Cross and Blue Shield of Minnesota, 9 10 Plaintiffs, File No. C1-94-8565 11 vs. 12 Philip Morris Incorporated, R.J. 13 Reynolds Tobacco Company, Brown 14 & Williamson Tobacco Corporation, 15 B.A.T. Industries P.L.C., Lorillard Tobacco Company, The American 16 17 Tobacco Company, Liggett Group, Inc., The Council for Tobacco Research-U.S.A., 18 19 Inc., and The Tobacco Institute, Inc., 20 Defendants. 2.1 22 TRANSCRIPT OF PROCEEDINGS 23 VOLUME 25, PAGES 4789 - 5058 24 FEBRUARY 23, 1998 25 STIREWALT & ASSOCIATES P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1953 DIRECT EXAMINATION - JAMES F. GLENN 4790 PROCEEDINGS. 1 2 THE CLERK: All rise. Ramsey County 3 District Court is now in session, the Honorable Kenneth J. Fitzpatrick presiding. 4 (Jury enters the courtroom.) 5 THE CLERK: You may be seated. 6 THE COURT: Good morning. 7 (Collective "Good morning.") 8 9 THE WITNESS: Good morning, sir. 10 THE COURT: Good morning. All right, counsel. 11 MR. WEBER: Thank you, Your Honor. 12 Good morning, ladies and gentlemen. 13 14 (Collective "Good morning.") 15 JAMES F. GLENN 16 called as a witness, being previously 17 sworn, was examined and testified as 18 follows: 19 DIRECT EXAMINATION (cont'd) 20 BY MR. WEBER: 21 Q. Good morning, Dr. Glenn. 22 A. Good morning, Mr. Weber. 23 Q. Dr. Glenn, when we stopped last Friday, we had 24 discussed your background and credentials, the 25 organization of the CTR, and the membership of the STIREWALT & ASSOCIATES P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1953 DIRECT EXAMINATION - JAMES F. GLENN 4791 Scientific Advisory Board. Do you remember? 1 3 Q. I want to start today discussing the research

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grant program of the Scientific Advisory Board, and
 4
    the first question I'll have for you is whether the
 5
    CTR over the years has published reports summarizing
 6
7
    the research activity of its grantees?
    A. Yes, sir. There has been an annual report since
8
9
    the very beginning of -- of CTR, or TIRC. The annual
    report embraces policy statement, introduction,
10
11
    summary of activities of the preceding year, and then
    abstracts of all of the articles published by
12
13
    investigators who were supported by CTR during that
    year, and finally an index of all investigators in
14
    the current volume and all prior investigators.
              MR. WEBER: Your Honor, may I approach the
16
17
    witness with this set of exhibits?
18
              (Box of documents handed to the witness.)
19
         Dr. Glenn, I know you've looked through that box
20
    before. Would you confirm that that includes
21
    originals or copies of the annual reports of The
    Council for Tobacco Research?
23
    A. Yes. These are -- are typical annual reports of
24
    CTR.
              MR. WEBER: Your Honor, let me hand up
25
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    Exhibit 50002, and at this time I would move the
1
    admission through Exhibit 50002 of the annual reports
 2.
    of The Council for Tobacco Research.
 3
 4
              MR. CIRESI: We have no objection, Your
 5
    Honor, subject to verification that each exhibit
    relates to the specific annual report.
 6
7
              THE COURT: Are you going to read through
8
    all those, counsel?
9
              MR. CIRESI: I don't think so, Your Honor.
10
    I think I'll just check to make sure the year is the
11
    same as the number.
              THE COURT: Court will receive 50002.
12
    BY MR. WEBER:
13
14 Q. Dr. Glenn, would you turn to Exhibit MD000084,
    which is one of the CTR annual reports. I believe
    it's the 1992 annual report.
16
    A. Yes, sir.
17
        And using the 1992 annual report, I'd like you
18
19
    to describe briefly for the jury the contents of an
20
    annual report.
21
        First of all, sir, is that the typical format
22
    for a CTR annual report during your tenure at CTR?
23
    Α.
24
    Q.
        Now could you hold up the annual report for 1992
25
    to the ladies and gentlemen of the jury so they could
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    see what we're talking about.
 1
        (Witness complies.)
    Α.
 2
 3
         Thank you.
         Now inside the front cover, Dr. Glenn, is a
 4
 5
   document called "Organiation and Policy." Correct?
   A. Yes.
 6
 7
    Q. And could you --
         Is there anything in the organization and policy
```

- 9 you'd like to function -- or to mention specifically
- 10 to the ladies and gentlemen of the jury?
- 11 A. Well I think there are several important points
- 12 here: it dates our origin back to 1954; it states
- 13 that our support is from the tobacco manufacturers,
- 14 growers and warehousemen; states that the program has
- been one of grants-in-aid, which is research grants,
- 16 supplemented by contracts for research with
- 17 institutions and laboratories; states that the
- 18 council does not operate any research facility;
- 19 states that the Scientific Advisory Board meets
- 20 regularly to judge the grant applications; and it
- 21 states that the council awards research grants to
- 22 independent scientists who are assured complete
- 23 scientific freedom in conducting their studies, and
- 24 the grantees are responsible for reporting or
- 25 publishing their findings in the accepted scientific STIREWALT & ASSOCIATES
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- 1 manner.
- 2 Q. Dr. Glenn, could you continue to the table of
- 3 contents page.
- 4 A. Yes, sir.
- 5 Q. Bring that up just a little, if you could.
- 6 Okay.
- 7 Now does this describe the -- or set forth
- 8 what's contained within the annual report?
- 9 A. Yes, it does.
- 10 Q. Now it refers in the -- two of those early lines
- 11 to abstracts. Do you see that?
- 12 A. Yes.
- 13 Q. What is an abstract in the scientific
- 14 literature?
- 15 A. Well the abstract is a summary of a paper, and
- 16 virtually every journal requires that there be an
- 17 abstract paragraph by the authors of the study. The
- 18 abstract details the reason for the research, the
- 19 methods used in the research, the results and the
- 20 author's conclusions from those results. Those
- 21 abstracts are published with the paper. We simply
- 22 take the abstract from the paper and use it as a
- 23 report in the -- in the journal.
- 24 Q. So the abstracts that are reprinted in the CTR
- 25 annual report are simply reprints of abstracts from STIREWALT & ASSOCIATES
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- 1 the scientific literature.
- 2 A. Yes.
- ${\tt 3}$ Q. And down at the bottom of this table of
- 4 contents, does it show in each annual report a list
- of all active projects?
- 6 A. Yes, sir.
- 7 Q. And does it have a list of all completed
- 8 projects over the years?
- 9 A. Yes, sir.
- 10 Q. And does it have an index of the principal
- 11 investigators over the years?
- 12 A. It does.
- 13 Q. Could you turn, Dr. Glenn, to the introduction

- 14 page.
- 15 A. Yes.
- 16 Q. Now as of 1992, approximately 204 million
- 17 dollars had been spent in the council's research
- 18 program; correct?
- 19 A. That's correct.
- 20 Q. Now it talks -- if we go down to the next
- 21 paragraph that begins "Eighty-three...," could you
- 22 read that paragraph to the ladies and gentlemen of
- 23 the jury.
- 24 A. "Eighty-three original projects were approved in
- 25 1992; many more continuing and renewal studies also STIREWALT & ASSOCIATES
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- 1 were funded. To date, a total of 1,329 original
- 2 investigations have been reported -- supported by the
- 3 council. Recipients for these are 932 independent
- 4 scientists at more than 300 medical schools,
- 5 hospitals and research centers."
- 6 Q. Now the next paragraph, Dr. Glenn.
- 7 A. "Council grantees published 342 reports on their
- 8 supported research during the year. Abstracts of
- 9 these are included in this report. The total for
- 10 such publications now is at least 4,770."
- 11 Q. Now has that number grown for published reports
- 12 since 1992?
- 13 A. Yes, incrementally each year.
- 14 Q. Now could you turn, I believe, to the next page,
- 15 Dr. Glenn -- or excuse me, go to page 21, if you
- 16 would, please.
- 17 A. Yes, sir.
- 18 Q. And that page at the top is entitled "Abstracts
- 19 of Reports?"
- 20 A. Yes, sir.
- ${\tt Q.}$ And that begins the reprints of the abstracts,
- 22 and they're broken down by subject matter; correct?
- 23 A. Correct.
- 24 Q. And the first one, just as an example, I'd like
- 25 you to focus on is this one which relates to the $$\operatorname{\mathtt{STIREWALT}}$$ & ASSOCIATES
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- 1 first in a series of cancer-related studies.
- 2 A. Yes, sir.
- 3 Q. Now are they listed --
- 4 Are the abstracts listed alphabetically by the
- 5 name of the grantee?
- 6 A. Yes, they are.
- 7 Q. Now this first one that's -- the beginning of
- 8 which is "Malignant Epithelial Cells," do you see
- 9 that?
- 10 A. Yes, sir.
- 11 $\,$ Q. Down at the bottom, does that indicate who the
- 12 grantee is?
- 13 A. Yes. This was Dr. Harry Antoniades, who was a
- 14 professor at Harvard University Medical School.
- 15 Q. Now --
- And then does the next line advise as to where
- 17 this research was published?
- 18 A. It was published in the Proceedings of the

- 19 National Academy of Sciences in May 1992.
- 20 Q. Is the National -- Proceedings of the National
- 21 Academy of Sciences one of the most prestigious
- 22 scientific journals in the world?
- 23 A. Yes, sir.
- 24 Q. Have SAB members over the years been members of
- 25 the National Academy of Sciences?

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- 1 A. Yes, sir.
- 2 Q. Now was this research grant here supported by
- 3 funding from any other research institute?
- A. It is noted that other support in addition to
- 5 CTR was from the National Institutes of Health.
- 6 Q. Now when CTR reprints these abstracts and talks
- 7 about other support, where do they get the
- 8 information as to who else has funded this research?
- 9 A. This comes from the paper itself. The
- 10 investigators will have a footnote on the paper that
- 11 says support for this research work came from the
- 12 following sources, and it may say CTR grant number
- 13 such and such, may say NIH and give the grant number,
- 14 may say American Heart, American Lung, or whatever
- 15 the source of other funding may be. Sometimes there
- 16 are several sources.
- 17 Q. Now does this reprinting of abstracts continue
- 18 by category throughout the report?
- 19 A. I'm sorry, Mr. Weber?
- 20 Q. Does the reprinting of the abstracts by category
- 21 continue throughout the report?
- 22 A. Yes, sir.
- 23 Q. Could you turn back to the table of contents for
- 24 a moment, Dr. Glenn.
- 25 A. Yes, sir.

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- 1 Q. And does that show that there are approximately
- 2 26 pages of abstracts on cancer-related studies?
- 3 A. Yes, sir.
- 4 Q. And approximately 14 on the respiratory system?
- 5 A. Yes, sir.
- 6 Q. Approximately 36 on heart and circulation?
- 7 A. Yes.
- 8 Q. Approximately ten on neuropharmacology and
- 9 physiology?
- 10 A. Yes.
- 11 Q. And approximately 103 on pharmacology,
- 12 biochemistry and cell biology?
- 13 A. Yes.
- 14 Q. And approximately 28 on immunology and adaptive
- 15 mechanisms?
- 16 A. That's correct.
- 17 Q. And when listing the active projects, is that
- 18 approximately 24 pages to list?
- 19 A. Yes.
- 20 Q. And completed projects, about 25 pages or so?
- 21 A. Yes, sir.
- MR. CIRESI: Your Honor, all the questions
- 23 are leading, and I don't know if this is preliminary,

going to something, but I'm going to object to the 24

25 leading nature of the questions.

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THE COURT: Well they are leading, but I 1

2 consider it just preliminary.

- 3 BY MR. WEBER:
- Now let's discuss how the grant process works 4 Ο.
- that leads to the funding of this research, if we 5
- could, Dr. Glenn. 6
- 7 When the SAB approves an application and advises
- The Council for Tobacco Research that it should be 8
- 9 funded, is the funding provided directly to the
- 10 researcher?
- A. No, no. The funding goes to the institution in 11
- 12 which the investigator is employed. The responsible
- 13 fiscal authority for the grant will be the
- institution. For example, with the grant to Dr. 14
- 15 Antoniades, the grant in that case, I think, was to
- the Harvard School of Public Health, and they are 16
- 17 responsible for reporting on expenditure of funds.
- 18 Q. When a researcher applies for a grant, what are
- 19 they advised as to the policy of the CTR as to
- 20 publication of research results?
- Well they're universally advised that they are 21 A.
- encouraged to publish their results, and specifically 22
- to report in accepted peer-reviewed journals. 2.3
- 24 Q. Is the application for a grant a two-step
- 25 process, doctor?

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- Α. Yes, sir. 1
- 2 Q. Could you describe that.
- Well generally an investigator will learn of CTR 3 Α.
- as a source from one of its colleagues or perhaps at 4
- 5 a medical meeting where someone mentions support by
- CTR. They then will contact us by telephone or by 6 7
- letter, and we have response to them that indicates that we would like to see a preliminary proposal, 8
- 9 which would be a two- or three-page letter, not in
- 10 great detail or great depth. That preliminary
- 11 inquiry, then, is circulated to members of the Scientific Advisory Board, and if they feel like it's 12
- 13 within our area of interest; that is, a project that
- 14 we would want to support, then the investigator is so
- 15 advised and encouraged to develop the full grant
- 16 application, which sometimes may run to 20 or 30
- 17 pages. So it's quite a bit of work to put together a 18 grant application.
- 19 In that application, that second application,
- 20 the final application, they will detail the project,
- 21 they will give a bibliography of background
- 22 information that's necessary to develop their --
- their thesis, they will tell us of the methodology 23
- they intend to use, they will tell us who else will 24 25 be involved in the project, they'll provide a brief

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- 1 resume of their own credentials and those -- and the
- 2 credentials of the others who work with them, and
- 3 then finally they will present us with a budget for
- 4 the project, detailing how they would expend the
- 5 funds that they're requesting.
- 6 Q. Dr. Glenn, could you briefly outline for the
- 7 jury the criteria applied by the SAB when they
- 8 receive a final application.
- 9 A. Well I think the first criterion, of course, is
- 10 merit, is this project worthy of support in the -- in
- 11 the view of the scientists who do the review?
- 12 Secondly, I think they would consider whether this
- is -- will add to the general body of knowledge in
- 14 the particular field. I think they also consider its
- 15 relevance to issues of smoking and health; that is to
- 16 say, is this a fundamental problem that will shed
- 17 light on the fundamental disease processes that are
- 18 going on in those diseases that are statistically
- 19 associated with smoking? They will look clearly at
- 20 the qualifications of the investigator. They look at
- 21 the quality of the institution from which the
- 22 application comes. They make certain that the
- 23 laboratory facilities and equipment are available and
- 24 appropriate to the study that's being proposed. And
- 25 I think those -- that covers generally the field that STIREWALT & ASSOCIATES
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- 1 they would examine.
- 2 Q. During your tenure at the CTR, has the
- 3 Scientific Advisory Board discussed factors such as
- 4 legal implications, public relations implications, or
- 5 whether the companies themselves would approve or not
- 6 approve of the research?
- 7 A. No, sir.
- 8 Q. Is the Scientific Advisory Board in fact an
- 9 Advisory Board?
- 10 A. It is.
- 11 Q. How -- how does that work?
- 12 A. Well obviously the final decision about the
- 13 amount of funding is left to our staff and the
- 14 administrative process. The Scientific Advisory
- 15 Board ranks the grant applications according to the
- 16 criteria we've discussed. This ranking is a
- 17 numerical ranking. Each member of the SAB votes on a
- 18 scale of one to five. Clearly we can develop a -- an
- 19 average score for each grant application that gives
- 20 us a ranking system. The staff then accepts the
- recommendations of the Scientific Advisory Board and may make adjustments to budget. For example, if an
- 23 investigator requests a very expensive piece of
- 24 equipment and in our view this is something that the
- 25 institution ought to undertake because it's going to STIREWALT & ASSOCIATES
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- 1 be a long-term acquisition for them, then we may say
- 2 please send us a revised budget indicating deletion
- 3 of this particular piece of equipment, and the
- 4 investigators will almost universally respond in that

- 5 way.
- 6 Q. Is there anyone who votes on the rankings other
- 7 than the SAB members?
- 8 A. No, sir.
- 9 Q. Are you aware of a committee that was in
- 10 existence at one time known as the Industry Technical
- 11 Committee?
- 12 A. Yes, sir.
- 13 Q. What was --
- 14 What's your understanding of what the Industry
- 15 Technical Committee was?
- 16 A. The Industry Technical Committee, I
- 17 think -- I -- I've never met with them or talked to
- 18 them about this, but I think --
- 19 MR. CIRESI: Objection, it calls for
- 20 speculation and conjecture.
- MR. WEBER: I'll lay some foundation.
- THE COURT: You'll have to lay some
- 23 foundation, counsel.
- 24 BY MR. WEBER:
- 25 Q. Given your experience at The Council for Tobacco STIREWALT & ASSOCIATES
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- 1 Research, have you come to gain an understanding from
- 2 its records and from the meetings you've attended as
- 3 to what was the Industry Technical Committee?
- 4 A. I have.
- 5 Q. Could you explain that, sir.
- 6 A. Industry Technical Committee --
- 7 MR. CIRESI: Excuse me.
- 8 A. -- was made up of representatives --
- 9 MR. CIRESI: Excuse me, doctor. Excuse me.
- 10 There still is no foundation. I don't know what
- 11 documents he's referring to.
- 12 THE COURT: Can you give us a little more,
- 13 please.
- 14 BY MR. WEBER:
- 15 Q. Dr. Glenn, have you, during your tenure at CTR,
- 16 met with an individual who was a representative of
- 17 the Industry Technical Committee?
- 18 A. I have met representatives of the Industry
- 19 Technical Committee, yes.
- 20 Q. Did industry -- members of the Industry
- 21 Technical Committee at any time attend meetings of
- the Scientific Advisory Board?
- 23 A. In my early tenure with CTR, the Industry
- 24 Technical Committee would send one representative to
- each meeting.

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- 1 Q. And have you come to understand about whether
- 2 the Industry Technical Committee would attend
- 3 meetings of the SAB in prior years?
- 4 A. As I understand it, they did.
- 5 Q. Can you explain to me what your understanding is
- of the Industry Technical Committee?
- 7 MR. CIRESI: Your Honor, I'm going to
- 8 object, again, because now he says that they
- 9 attended, and just before, at --

```
"Question: What was your understanding of what
11 the Industry Technical Committee was?
12
          "The Industry Technical Committee, I
13
    think -- I -- I've never met with them or talked to
    them about this, but I think --"
14
15
        And now he says that they were at meetings where
16
    he was at. There's still no foundation.
              THE COURT: All right.
17
18
              MR. WEBER: May I be heard?
19
              THE COURT: Yes.
              MR. WEBER: I mean he's made it clear that
20
21 he said he never met with the whole committee, but he
22 has met with representatives of the committee. They
23
    have attended meetings. He has a first-hand
    understanding of why they were there, and that's all
24
25
    I'm asking for, is him to explain that.
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              THE COURT: Okay. Are you going to be
 1
 2
    asking questions about their attendance at these
 3
    meetings here?
 4
              MR. WEBER: Yes.
 5
              THE COURT: Okay. Go head.
 6 BY MR. WEBER:
   Q. What was your understanding as to the role that
 7
    a representative of the Industry Technical Committee
 8
    played at meetings of the Scientific Advisory Board?
9
10
    A. The representative who came to the meetings was
11
    there only as a consultant in case any question arose
    as to research that was being accomplished by the
12
13
    industry, or to answer technical questions, usually
14 of a chemical nature.
   Q. Did any member of the Industry Technical
15
16 Committee ever vote on a grant application?
17
    A. No, sir.
   Q. Did company scientists ever vote on grant
18
19
    applications?
20 A. No, sir.
        By the way, would outside scientists from the
21 Q.
    public health community be invited from time to time
    to attend SAB meetings?
23
24
    A. Yes.
25
    Q. Can you explain that.
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    A. Well the CTR intended to maintain contact with
 1
    the general biomedical research community and with
    public health officials, and frequently there would
 3
 4
    be representatives from the American Heart
 5
    Association, American Cancer Society, the NIH,
    particularly the National Cancer Institute, who would
 7
    join the meetings. Not at voting members, but simply
    to be there for technical consultation if required.
 8
    Q. You mentioned NIH, Dr. Glenn.
 9
10
   A. Yes, sir.
11 Q. National --
        That's National Institute of Health?
12
13 A. Yes.
14 Q. Now in addition to the grant process, did CTR
```

- 15 sometimes fund research by contract?
- 16 A. Yes, sir.
- 17 Q. Was the contract research approved by the
- 18 Scientific Advisory Board?
- 19 A. Yes.
- 20 Q. Was it part of the Scientific Advisory Board's
- 21 research program?
- 22 A. Yes.
- 23 Q. Do other funding institutions use contracts
- 24 occasionally as well to fund research?
- 25 A. Yes. I think virtually every funding STIREWALT & ASSOCIATES
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- 1 organization uses the contract mechanism, including
- 2 agencies of the federal government, and the reason is
- 3 that generally the contract research that's -- that
- 4 is specified is of such magnitude, such size, that
- 5 one single laboratory or independent investigator
- 6 probably couldn't -- couldn't manage it himself. So
- 7 the contract work was usually limited to bigger
- 8 projects.
- 9 Q. And does the National Institute of Health use
- 10 contract research?
- 11 A. Yes.
- 12 Q. How does the amount of funded research that went
- 13 through the SAB program break down between grant
- 14 research and contract research?
- 15 A. I've forgotten the exact figures, but I -- I
- 16 think currently -- or in 1994 the amount of contract
- 17 research would constitute less than five percent of
- 18 the total budget.
- 19 Q. So the vast majority has been the grant program.
- 20 A. Yes.
- 21 Q. Dr. Glenn, what is CRT's policy regarding the
- 22 publication of research results undertaken by
- 23 researchers that the CTR SAB has funded?
- 24 A. Policy is that the -- as stated in the policy
- 25 statement -- investigators are encouraged to present STIREWALT & ASSOCIATES
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- 1 and publish their results in the usual and accepted
- 2 scientific manner.
- ${\tt 3}\,{\tt Q}\,.\,\,\,$ Have the results of CTR-funded research appeared
- 4 in leading scientific journals throughout the world?
- 5 A. They have.
- 6 Q. Could you turn to tab 13, Dr. Glenn, and that is
- 7 Exhibit AM000204.
- 8 A. Yes, sir, I have that.
- 9 Q. And can you identify that as a listing of
- 10 journals and publications in which CTR research has
- 11 appeared?
- 12 A. I can, yes.
- MR. WEBER: Your Honor, I'd move the
- 14 admission of Exhibit AM000204.
- MR. CIRESI: No objection, Your Honor.
- THE COURT: Court will receive AM000204.
- 17 BY MR. WEBER:
- 18 Q. Now Dr. Glenn, that list is approximately 29
- 19 pages long?

- 20 A. It is.
- 21 Q. Let's start with U.S. journals and just go
- 22 through a few briefly.
- 23 Has research funded through the SAB appeared in
- 24 the Journal of the National Cancer Institute?
- 25 A. It has.

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- 1 Q. In a journal called Cancer?
- 2 A. Yes, sir.
- 3 Q. Is Cancer one of the world's leading journals?
- 4 A. Yes, sir.
- 5 Q. Cell?
- 6 A. Yes.
- 7 Q. Chest?
- 8 A. Yes.
- 9 Q. Circulation?
- 10 A. Yes.
- 11 Q. Immunology?
- 12 A. Yes.
- 13 Q. The Journal of Cell Biology?
- 14 A. Yes.
- 15 Q. The New England Journal of Medicine?
- 16 A. Yes, sir.
- 17 Q. In all the --
- 18 Would you say that the vast majority of the
- 19 leading U.S. medical journals have carried reports of
- 20 research funded by the CTR Scientific Advisory Board?
- 21 A. Yes, as documented here.
- 22 Q. How about international journals, have -- has
- 23 work funded by the CTR SAB program appeared in
- 24 international journals as well?
- 25 A. Numerous international journals.

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- 1 Q. Is The Lancet --
- 2 What's the reputation for a journal called The
- 3 Lancet in the medical community?
- 4 A. Lancet is one of the oldest medical journals.
- 5 It is a British journal. Probably I would have to
- 6 say if not the most respected, one of the most
- 7 respected journals in the world.
- 8 Q. Has research funded by CRT's SAB appeared in The
- 9 Lancet?
- 10 A. Yes.
- 11 Q. In the British Journal of Cancer?
- 12 A. Yes.
- 13 Q. British Medical Journal?
- 14 A. Yes.
- 15 Q. How about leading French and European journals?
- 16 A. There also.
- 17 Q. Italian journals?
- 18 A. Yes.
- 19 Q. Israeli?
- 20 A. Yes.
- 21 Q. Scandanavia?
- 22 A. Yes.
- 23 Q. Germany and Japan?
- 24 A. Yes, sir.

- 25 Q. Has the United States Public Health Service ever STIREWALT & ASSOCIATES
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- 1 cited research funded by the scientific Advisory
- 2 Board in its Surgeon General reports?
- 3 A. Yes. I think cumulatively probably 300, 350
- 4 times.
- 5 Q. To your knowledge, has The Council for Tobacco
- 6 Research ever suppressed the publication of research
- 7 it funded?
- 8 A. No.
- 9 Q. Let's discuss now briefly some of the
- 10 institutions where CTR-funded research has been
- 11 conducted and some of the researchers, starting right
- 12 here. Could you turn to tab 14, Dr. Glenn.
- 13 A. I have it.
- 14 Q. That's demonstrative Exhibit 1925B, as in blue.
- 15 Can you identify that document, Dr. Glenn? Is it a
- 16 demonstrative chart relating to funding in the state
- 17 of Minnesota?
- 18 A. It is. These are CTR grantees in the state of
- 19 Minnesota.
- 20 Q. Dr. Glenn, before you go ahead, I need to move
- 21 it into evidence.
- MR. WEBER: I'd like to move for
- 23 demonstrative purposes, Your Honor, the admission of
- 24 Exhibit 1925B.
- 25 MR. CIRESI: No objection, Your Honor. STIREWALT & ASSOCIATES
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- 1 THE COURT: Court will receive 1925B for
- 2 demonstrative purposes.
- 3 BY MR. WEBER:
- 4 Q. And can you describe just briefly what this is,
- 5 Dr. Glenn?
- 6 A. This is entitled "CTR Grantees in Minnesota."
- 7 Q. (Coughing) Excuse me.
- 8 And does it list those people who have received
- 9 grants from the Scientific Advisory Board and
- 10 conducted research in this state over the years?
- 11 A. It does.
- 12 Q. Has the CTR Scientific Advisory Board funded
- 13 research across the United States as well, Dr. Glenn?
- 14 A. Oh, it has, in virtually every state.
- 15 Q. Can you turn to tab 15. That's Exhibit 19 --
- 16 demonstrative Exhibit 1970.
- 17 A. Yes.
- 18 Q. Is that a chart demonstrative showing the
- 19 geographical spread of CTR grant research?
- 20 A. It is.
- 21 MR. WEBER: Your Honor, I'd move the
- 22 admission for demonstrative purposes of Exhibit 1970.
- MR. CIRESI: No objection, Your Honor.
- 24 THE COURT: Court will receive 1970 for
- 25 demonstrative purposes.

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- BY MR. WEBER: Q. Can we pull that up or not? Okay. Put 2. 3 the -- well, sorry I can't get that to look any 4 Is this a chart that represents funding across 5 6 the country? 7 A. This is a map of the United States, and representative grantee institutions are listed here. 8 9 This is not a complete list, but it does show the 10 geographic distribution of grants that have been made 11 over the years. 12 Q. Has CTR funded research of major United States universities? 13 14 Α. Yes. 15 Q. Let me go through just a representative list 16 with you. And answer "yes" or "no" on each one as to 17 whether research has been funded there through the 18 SAB. 19 At Duke? 20 A. Yes. 21 At Yale? Q. 22 Α. Yes. Q. 23 At Harvard? 24 A. Yes. 25 Q. MIT? STIREWALT & ASSOCIATES P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1953 DIRECT EXAMINATION - JAMES F. GLENN 4816 1 Α. Yes. Q. Stanford? 2. Yes. 3 Α. 4 Q. University of Chicago? 5 Α. Yes. University of Minnesota? 6 Q. 7 Yes. Α. 8 Ο. University of Wisconsin? A. 9 Yes. 10 Q. Iowa University? 11 A. Yes. 12 Q. University of Michigan? Yes. 13 A. Johns Hopkins? 14 Q. 15 Α. Yes, sir. 16 Q. Penn? 17 A. Yes. 18 Q. University of California? 19 A. Yes. 20 Q. Cornell? Yes. 21 Α. 22 Q. Many others? Yes. A. 23 24 Q. Has CTR also funded research at major biomedical 25 research institutions in the United States and STIREWALT & ASSOCIATES P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1953 DIRECT EXAMINATION - JAMES F. GLENN 4817 abroad? 1 2 A. It has. Q. At the Dana Farber Institute? 3 4 A. Yes.
- http://legacy.library.ucsf&dw/tid/zstp@5a00/pdfndustrydocuments.ucsf.edu/docs/kxxd0001

Q. Where is that located, doctor?

- 6 A. In Boston.
- 7 Q. And what is that?
- 8 A. It is a research institute that is affiliated
- 9 with the Harvard Medical School and several of the
- 10 Harvard hospitals.
- 11 Q. At the Mayo Clinic?
- 12 A. Yes.
- 13 Q. At the Fox Chase Cancer Center?
- 14 A. Yes.
- 15 Q. What is the Fox Chase Cancer Center?
- 16 A. Fox Chase is an independent cancer research
- 17 institution which has affiliations with the
- 18 Philadelphia Medical School.
- 19 Q. At the Scripps Institute?
- 20 A. Yes.
- 21 Q. Is that a major funder and performer or --
- Is that a major research institution?
- 23 A. It is, and -- and a major clinical institution
- 24 as well, the Scripps Clinic and Scripps Hospital.
- 25 Q. And has CTR funded research in overseas research STIREWALT & ASSOCIATES
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- 1 institutions?
 - A. Yes.
- 3 Q. Including the Karolinska Institute?
- 4 A. Yes.
- 5 Q. Where is that located?
- 6 A. In Stockholm, Sweden.
- 7 Q. Are you generally familiar with the reputations
- 8 of the institutions and investigators and researchers
- 9 who have been funded through the SAB grant program?
- 10 A. I am.
- 11 Q. And what is that reputation in the biomedical
- 12 community?
- 13 A. Well, I think, you know, these are the top
- 14 institutions, and the investigators have been of
- 15 first-rank quality, respected by their peers,
- 16 acknowledged by the biomedical research community to
- 17 be outstanding contributors.
- 18 Q. You mentioned on Friday that one SAB member had
- 19 been nominated for a Nobel Prize?
- 20 A. Well as a matter of fact three of them have.
- 21 Q. Members of the Scientific Advisory Board over
- 22 the years?
- 23 A. Yes.
- 24 Q. Have any of the CTR grantees ever been nominated
- 25 for the Nobel Prize?

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- 1 A. Yes, many of them, and three of them have --
- 2 have won the Nobel Prize.
- 3 Q. Can you identify these grantees of CTR who have
- 4 won Nobel Prizes?
- 5 MR. CIRESI: Objection, Your Honor, it's
- 6 irrelevant.
- 7 THE COURT: Oh, you may answer that.
- 8 THE WITNESS: Answer it, Your Honor?
- 9 THE COURT: Yes.
- 10 A. Dr. Baruch Benacerraf at Harvard won the Nobel

- 11 Prize. We supported Dr. Benacerraf for a number of
- 12 years. His work was in the area of molecular
- 13 biology. He's really considered to be a pioneer of
- 14 molecular biology.
- 15 Second one was Dr. Stanley Cohen, whose work
- 16 was with growth factor. Dr. Cohen is professor at
- 17 Vanderbilt University Medical School in Nashville.
- 18 Dr. Cohen was the person who really opened up the
- 19 field of growth factor. Growth factor is a substance
- 20 that is virtually essential for cell proliferation,
- 21 for cell growth.
- 22 And the third individual who won the Nobel Prize
- 23 for his work in oncogenes, the cancer-causing gene,
- 24 was Dr. Harold Varmus, who was then professor at the
- 25 University of California-San Francisco, but who is STIREWALT & ASSOCIATES
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4 Q 2 N

- now the director of the National Institutes of
- 2 Health.
- 3 Q. And were these researchers awarded their Nobel
- 4 Prizes for research in areas that included the areas
- 5 that CTR had funded them in?
- 6 A. Yes, sir.
- 7 Q. Do CTR grantees typically get all of their
- 8 research funding from CTR?
- 9 A. Oh, no. As a matter of fact, our funding many
- 10 times was in the form of seed money, something to
- 11 help get a project started. Our grants were not huge
- 12 grants for the most part, 80, 85 thousand dollars a
- 13 year, but it would get an investigator started on a
- 14 given project. And usually those that were off to a
- 15 successful start could then attract major funding
- 16 from federal funding sources.
- 17 Q. How does CTR know who -- what other institutions
- 18 may be funding a researcher that they're funding?
- 19 A. Well in the grant application an investigator is
- 20 asked to list the sources of funding that he has
- 21 currently, as well as pending funding; that is, where
- 22 he may have applied for additional funding, and of
- 23 course when we receive the report from the
- 24 investigator year by year, we know what other funding
- 25 he's gotten because he tells us.

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- 1 Q. And is it also disclosed in publications
- 2 eventually?
- 3 A. Yes, as we discussed.
- 4 Q. And is it of any significance to those of you
- 5 affiliated with CTR and the Scientific Advisory Board
- 6 as to the fact that researchers funded through the
- 7 SAB program are also getting funding from other
- 8 sources?
- 9 A. Well I think it's reassurance that our judgment
- 10 was correct in the first place.
- 11 Q. Let me turn now to some changes in CTR over the
- 12 years, if I might, Dr. Glenn.
- During your tenure at CTR, has CTR engaged in
- 14 any active public information, public affairs, public
- 15 relations activities?

- 16 A. No.
- 17 Q. Does CTR send out routine press releases any
- 18 more in your tenure?
- 19 A. Once a year we send a brief press release
- 20 announcing the publication of the annual report, and
- 21 it usually -- this little, brief blurb usually says
- 22 how much money we have expended for research grants
- $\,$ 23 $\,$ during the -- the past year, the number of grantees $\,$
- 24 that we've supported, and the cumulative experience
- 25 in supporting biomedical research, and that's about STIREWALT & ASSOCIATES
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- 1 the size of it.
- 2 Q. And are the annual reports distributed to
- 3 medical schools and medical libraries throughout the
- 4 country?
- 5 A. Every medical school in North America, the deans
- 6 of all the medical schools; also to all of our
- 7 current and former grantees, we send a copy of the
- 8 annual report so they can see for themselves the
- 9 progress; these reports are also sent to major
- 10 newspapers along with the brief press release.
- 11 Q. Based on your understanding of the history of
- 12 CTR -- and I know you don't know everything, but
- 13 based on what you do know -- do you know whether CTR
- 14 in its earlier years played a more active or
- 15 different role with respect to public information and
- 16 press activity?
- 17 A. Yes, they were more active.
- 18 Q. And did that activity diminish over time?
- 19 A. It did.
- 20 $\,$ Q. Could you explain that for us in terms of your
- 21 understanding.
- 22 A. Well in the beginning, you know, under the terms
- 23 of the Frank Statement, the TIRC, later the CTR, was
- 24 charged with not only supporting an investigative
- 25 program, but also with making public the information STIREWALT & ASSOCIATES
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- that was developed. By just -- within just a few
- 2 years it was recognized that the public information
- 3 charge was more appropriately done by another agency,
- 4 and The Tobacco Institute was formed, and it
- 5 gradually took over the function of public
- 6 information.
- 7 Q. Do other research funders and other research
- 8 institutions have public affairs or public relations
- 9 offices?
- 10 MR. CIRESI: Objection, foundation,
- 11 hearsay, irrelevant.
- 12 THE COURT: Sustained.
- 13 Q. Dr. Glenn, have the academic institutions and
- 14 hospitals that you've been associated with over the
- 15 years also had public relations or public affairs
- 16 offices?
- 17 MR. CIRESI: Objection, irrelevant.
- 18 THE COURT: Sustained.
- 19 Q. Dr. Glenn, what function, based on your
- 20 knowledge, do public affairs or public information

```
offices that are affiliated with universities or
22
    research institutions serve?
23
              MR. CIRESI: Objection, irrelevant,
24
    foundation.
              THE COURT: Sustained.
25
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         Dr. Glenn, to your knowledge, did any public
 1
    Q.
    relations activity at CTR affect the quality of any
    research that was being done?
    A. No, sir.
 4
        Let me ask now about another change over the
 5
    Q.
    years. Did CTR once fund research through what was
 7
    called CTR special projects?
    A.
         Yes.
8
   Q. When did CTR special projects begin, Dr. Glenn?
9
10 A. I believe in about 1965.
11 Q. Do you know when they ended?
    Α.
        About 1990.
12
        Was the CRT's scientific director involved at
13
    Ο.
    all in approving CTR special projects?
14
    A. Yes. The scientific director reviewed every
15
    special -- CTR special project that was proposed by
16
17
    the sponsors, reviewing it primarily for scientific
    merit, whether he thought it would add anything to
18
    the body of knowledge in the -- in the general field.
19
20
        Did you approve any research of CRT's special
2.1
    projects when you were scientific director?
22
    A. Not new projects, because the project -- the
23
    special projects of CTR were gradually winding down.
24
    I did approve a renewal of one of the CTR special
25
    projects.
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        Do other funding institutions such as the
    Ο.
 1
    National Institutes of Health use the term "special
    projects" to designate certain of their research?
              MR. CIRESI: Objection, Your Honor, it's
 4
    irrelevant, there's no foundation.
 5
 6
              THE COURT: Sustained.
7
              MR. WEBER: Let me ask -- let me see if I
8
    can lay some foundation here, Your Honor.
9
              MR. CIRESI: Your Honor, I'm going to
10
    object also on irrelevance.
11
              THE COURT: Okay. I don't know what that
12
    has got to do with this case, counsel. Why don't you
13
14
              MR. WEBER: Can I -- well can I try to ask
15
    one question, see if I can address this, Your Honor?
16
    I think it might address the court's concern.
17
              THE COURT: Okay.
18
    BY MR. WEBER:
    Q. Does the term "special project" or "National
19
20
    Institute of Health special project" have a
    recognized meaning in the research community?
21
22
    A. It does.
23
              MR. CIRESI: Objection. Excuse me, doctor.
24 It's irrelevant.
25
              THE COURT: No, you may answer that.
```

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- 1 Q. Dr. Glenn, would you like the question again or 2 do you remember it?
- 3 A. I remember the question.
- 4 Q. Okay.
- 5 A. The National Institutes of Health does have a
- 6 public relations function and they do --
- 7 MR. CIRESI: Your Honor, --
- 8 MR. WEBER: No, --
- 9 MR. CIRESI: -- that's not --
- 10 MR. WEBER: -- that was not the question.
- MR. CIRESI: Excuse me.
- 12 THE COURT: Okay. Do you want to try --
- MR. CIRESI: He's given an answer to a
- 14 different question. I don't know where that came
- 15 from.
- 16 THE COURT: Okay. Do you want to try it
- 17 again, counsel?
- 18 MR. WEBER: Yeah, I'll ask it again.
- 19 THE COURT: Okay.
- 20 BY MR. WEBER:
- 21 Q. Dr. Glenn, does the term "special project" or
- 22 "National Institute of Health special project" have a
- 23 recognized meaning in the medical research community?
- 24 A. Yes.
- 25 Q. What does that mean to those of you in the STIREWALT & ASSOCIATES
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- 1 medical research community?
- 2 MR. CIRESI: Again, Your Honor, I'm going
- 3 to object on relevance grounds.
- 4 THE COURT: No, you may answer that.
- 5 A. Special projects are projects supported by the
- 6 NIH or another agency with a specific purpose. It's
- 7 more in the line of contract research than it is the
- 8 usual competitive grant-in-aid.
- 9 Q. Were CTR special projects handled separately
- 10 from the SAB grant program?
- 11 A. Yes.
- 12 Q. Were CTR special projects reported in the annual
- 13 report?
- 14 A. No.
- 15 Q. Did funds for CTR special projects come out of
- 16 the or take away from the Scientific Advisory Board's
- 17 research budget?
- 18 A. No. They were independently funded.
- 19 Q. How did the amount spent on CTR special projects
- 20 over the years compare to that spent on -- the money
- 21 spent in the grant program?
- MR. CIRESI: Objection, Your Honor, it's
- 23 already been testified to. We put a document in on
- 24 his cross-examination with regard to it.
- 25 THE COURT: Okay. I think we covered it STIREWALT & ASSOCIATES
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 - once. I'll -- I hope we aren't going to go into

```
2
    depth again; are we?
              MR. WEBER: No, we're not.
 3
              THE COURT: Okay. Go ahead.
 4
 5
         Go ahead, do you remember --
        I don't remember the exact figures, but it
 6
7
    amounts to only a fraction of the total SAB grant
    funds.
8
9
    Q. Did you understand that CTR special projects
10
    were suggested by the sponsors of CTR?
11
    A. Yes.
     Q. Do you know whether lawyers may have suggested
12
    some of those projects to the sponsors?
              MR. CIRESI: Objection, Your Honor, he
14
    testified last Friday he didn't know.
15
16
              THE COURT: Okay.
              MR. WEBER: Well may I respond?
17
              THE COURT: You're going to respond to
18
19
    counsel?
20
              MR. WEBER: Yes.
              THE COURT: I thought we were going to have
21
22 a question and answer between the attorney and the
23
    witness. Okay.
              MR. WEBER: Yes, I'm sorry.
2.4
25
              THE COURT: If you have a question, ask the
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 1
    witness.
 2
              MR. WEBER: I'm sorry, I didn't hear the
    ruling on that, Your Honor.
 3
              THE COURT: Okay. The ruling is overruled.
 4
 5
              MR. WEBER: Excuse me. I'm still a little
 6
    stuffed up, so I -- excuse me.
7
    BY MR. WEBER:
    Q. Do you remember the question, Dr. Glenn?
8
9
    Α.
         No.
10
    Q. Okay. Did you have an understanding as to
    whether lawyers may have been people who suggested to
11
12
    the sponsors that certain special projects be done?
13
    A. I didn't understand that, but it's not
    unreasonable that they would have been consulted.
14
15
    Q. Does the fact that the sponsors or perhaps even
    their lawyers may have suggested that certain
16
17
    research be funded make that research itself
18
    unreliable?
19
             MR. CIRESI: Objection, it's speculation,
20
    there's no foundation for this witness.
              THE COURT: Well what you're -- you are
21
    getting very leading, counsel. I wonder if you
22
23
    could --
              MR. WEBER: Okay.
24
25
              THE COURT: -- make your questions a little
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 1
    more general.
 2
    BY MR. WEBER:
 3
    Q. Does -- how do scientists -- strike that. Does
 4
   the --
        Does who sponsored the research control the
    question of whether research is reliable or not?
```

- 7 A. No.
- 8 MR. CIRESI: Excuse me, doctor. Your
- 9 Honor, I'm going to object to that. Whose research?
- 10 In what year? There's no foundation, it's vague and
- 11 overbroad.
- 12 THE COURT: I expect you will ask him
- 13 something more specific. I'll allow the question and
- 14 you may answer it.
- 15 A. No, sir.
- 16 Q. Go ahead.
- 17 A. The source of funding does not dictate the
- 18 quality or the type of research.
- 19 Q. In your 46 years in academic medicine and being
- 20 involved in research and being on funding
- 21 organizations, do you have an understanding as to how
- 22 scientists judge the quality of published research?
- 23 A. Yes.
- 24 Q. How is that done?
- 25 A. Well the presentation of scientific research may STIREWALT & ASSOCIATES
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- 1 be in the form of a verbal presentation, oral
- 2 presentation at a medical meeting. Papers to be
- 3 presented at a medical meeting are reviewed by a
- 4 committee of peers, of people who are knowledgeable
- 5 in that area. And it's competitive. They are not
- 6 going to accept -- at a qualified medical meeting
- 7 they will not accept presentation of shoddy or
- 8 inaccurate research.
- 9 The same thing holds true for publication. The
- 10 articles submitted for publication in these hundreds
- 11 of medical journals are reviewed by an editorial
- 12 board of peers, people who are knowledgeable in the
- 13 field, and those papers that are -- are not of
- 14 quality are rejected.
- 15 Q. Dr. Glenn, have you come --
- 16 Do you have an understanding as to why CTR
- 17 special projects were funded through CTR?
- 18 A. Yes.
- 19 Q. Could you explain that.
- 20 A. I think it was purely a matter of convenience.
- 21 The funding mechanism in medical research
- 22 institutions, medical schools, clinics, hospitals, is
- 23 different from the usual course of business. Each
- 24 institution will have a grants and contracts office,
- 25 and they will have a financial officer that is in STIREWALT & ASSOCIATES
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- 1 charge and is responsible for receiving the funds.
- 2 CTR staff were accustomed to dealing with
- 3 institutions and providing the funds and receiving
- 4 reports of expenditure of funds, so it was a
- 5 convenience for the sponsor companies simply to fund 6 these special projects of CTR through the CTR
- these special projects of the thir
- 7 offices.
- 8 Q. Has CTR compiled a list from its records of
- 9 CRT's special projects?
- 10 A. Yes.
- 11 Q. Could you turn to tab 16, Dr. Glenn, and that

- 12 would be Exhibit AM005003.
- 13 A. Yes, I have it.
- 14 Q. Can you identify that as a list from CRT's
- 15 records of CRT's special projects?
- 16 A. Yes.
- MR. WEBER: Your Honor, I'd move the
- 18 admission of Exhibit AM005003, a list of special
- 19 projects of CTR.
- 20 MR. CIRESI: I have no objection to this,
- 21 Your Honor.
- THE COURT: Court will receive AM005003.
- MR. WEBER: (Coughing) Excuse me.
- 24 BY MR. WEBER:
- 25 Q. Approximately how many CTR special projects were STIREWALT & ASSOCIATES
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- 1 there, Dr. Glenn?
- 2 A. Approximately 110.
- 3 Q. Were all CTR special projects original
- 4 laboratory or scientific research?
- 5 A. Not in the early days. I think there were some
- 6 focus studies that were epidemiological surveys,
- 7 literature reviews, but toward the end of the special
- 8 projects they were original research, yes.
- 9 Q. Did CTR have a policy regarding the publication
- 10 of research results resulting from original research
- 11 in CRT's special projects?
- 12 A. Yes.
- 13 Q. What was that policy?
- 14 A. The same policy that we had for grants and
- 15 contracts, and that was that publication was the
- 16 responsibility of the investigator, and they were
- 17 encouraged to -- to present or publish their work in
- 18 the standard scientific manner.
- 19 Q. Dr. Glenn, could you turn to tab 17.
- 20 MR. WEBER: And Your Honor, may I approach?
- 21 It's another composite exhibit list.
- Do we have a copy for Mr. Ciresi?
- 23 BY MR. WEBER:
- Q. Dr. Glenn, does tab 17 collect funding letters
- 25 to researchers receiving CTR special projects? STIREWALT & ASSOCIATES
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- 1 A. Yes, sir.
- Q. And is that a complete collection of the letters
- 3 that exist in informing a researcher of their
- 4 approval as a special project for CTR as from the
- 5 files of CTR?
- 6 A. Yes, it does.
- 7 MR. WEBER: Your Honor, I'd move the
- 8 admission through Exhibit 50003, which lists numbers,
- 9 of the exhibits listed thereon.
- MR. CIRESI: Once again, Your Honor, we
- 11 have no objection in order to expedite matters, so
- 12 long as we have an opportunity to verify.
- 13 THE COURT: All right. Court will receive
- 14 Exhibit 50003.
- 15 BY MR. WEBER:
- 16 Q. Now Dr. Glenn, could you turn within tab 17 to

- 17 the exhibit listed MD001076.
- 18 A. It's going to take me a long time to find that,
- 19 counselor.
- 20 Q. Well why don't we do it this way then. Why
- 21 don't you --
- 22 Oh, these are the numbers on the left-hand side,
- 23 Dr. Glenn. That might make it easier.
- 24 A. Oh, I'm sorry.
- MR. WEBER: May I approach, Your Honor, to STIREWALT & ASSOCIATES
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- 1 speed this up?
- Q. See the exhibit numbers down here, Dr. Glenn?
- 3 Wait, you're almost there. MD001076. Do you see
- 4 that?
- 5 A. Correct.
- 6 Q. And I will ask you a couple more of these, and
- 7 that's where you'll find those numbers.
- 8 Can we bring that up?
- 9 Now is this a letter sent to a researcher who
- 10 was going to receive CTR special project funding?
- 11 A. Yes.
- 12 Q. And can you describe or read that letter and
- 13 explain its purpose at CTR.
- 14 A. Well it's to Dr. Doris Herman in the Department
- of Pathology, University of Southern California in
- 16 Los Angeles, refers to a letter of May 25th
- 17 confirming the financial assistance which she had
- 18 requested. It's written by Dr. Hoyt, who said he
- 19 inadvertently failed to mention that our records will
- 20 designate your undertaking as a special project of
- 21 The Council for Tobacco Research rather than a
- 22 grant-in-aid, and it further tells her that if a
- 23 credit line should be inserted into any future
- 24 publication, it should be so worded in order to avoid
- 25 its being confused with the grant program of the STIREWALT & ASSOCIATES
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- 1 Scientific Advisory Board.
- Q. Now Dr. Glenn, could you continue on to
- 3 MD001108, which is another letter. And maybe to make
- 4 it quicker, Dr. Glenn --
- 5 A. I have it.
- 6 Q. Okay. And that's a letter to Dr. Macdonald?
- 7 A. No, sir, --
- 8 Q. Okay.
- 9 A. -- I don't have it.
- 10 Q. Why don't you look on the one on the screen
- 11 then. Is that 1108?
- 12 A. Yes.
- 13 Q. All right. That's a letter to Dr. Eleanor
- 14 Macdonald?
- 15 A. Yes.
- 16 Q. Okay. And again in that second-to-the-last
- 17 paragraph, could you read that?
- 18 A. "Our records will designate this undertaking as
- 19 a special project of The Council for Tobacco
- 20 Research-U.S.A., Inc., rather than a grant-in-aid.
- 21 If a credit line should be inserted into any future

- 22 publications, it should be worded to avoid its being
- 23 confused with the grant program of the Scientific
- 24 Advisory Board."
- 25 Q. All right. And are these examples we've seen STIREWALT & ASSOCIATES
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- 1 consistent with the types of letters that were sent
- 2 to special project recipients?
- 3 A. Yes. I -- I have reviewed many of these
- 4 letters, and they all contain similar wording.
- 5 Q. Generally they all contain that wording.
- 6 A. Yes.
- 7 Q. Now did CTR special project researchers in fact
- 8 publish their work?
- 9 A. Yes.
- 10 Q. Are the publications of CTR special projects,
- 11 research of which CTR is aware, listed in Exhibit
- 12 AM005003, which is at tab 16, and that's the list of
- 13 special projects that were admitted into evidence
- 14 just a little earlier?
- 15 A. Yes.
- 16 Q. And you've reviewed that list; haven't you,
- 17 doctor?
- 18 A. Yes, sir.
- 19 Q. Were the results of CTR special project research
- 20 generally published in quality scientific peer-review
- 21 journals?
- 22 A. Generally, yes.
- 23 Q. Did research funded of CTR special project
- 24 research include research undertaken at quality
- 25 institutions?

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- 1 A. Yes, sir.
- 2 Q. Can you turn to tab 18, which is Exhibit 1217.
- 3 A. I have it.
- 4 Q. And is that a representative -- demonstrative
- 5 chart representing some of the institutions that
- 6 received special project research?
- 7 A. Yes, sir.
- 8 MR. WEBER: Your Honor, I'd move the
- 9 admission of Exhibit 1217 for demonstrative purposes.
- MR. CIRESI: No objection, Your Honor.
- 11 THE COURT: Court will receive 1217 for
- 12 demonstrative purposes.
- 13 BY MR. WEBER:
- 14 Q. Now are these some of the institutions that have
- 15 received CTR special project funding, Dr. Glenn?
- 16 A. Some, but not all. This is not an inclusive
- 17 list.
- 18 Q. And are these quality research institutions?
- 19 A. Absolutely.
- 20 $\,$ Q. Did other quality funding organizations also
- 21 support research and researchers who were at the same
- 22 time being supported by CTR special project funding?
- 23 A. Yes.
- Q. Could you turn to tab 19, which is demonstrative
- 25 Exhibit 1218.

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- 1 A. I have it.
- Q. Is that a listing of some other organizations
- 3 that also funded CTR special project research?
- 4 A. It is.
- 5 MR. WEBER: Your Honor, I'd move the
- 6 admission of Exhibit 1218 for demonstrative purposes.
- 7 MR. CIRESI: No objection, Your Honor.
- 8 THE COURT: Court will receive 1218 for
- 9 demonstrative purposes.
- 10 BY MR. WEBER:
- 11 Q. Now how is it that CTR developed this
- 12 representative list of other organizations that were
- 13 funding CTR -- were funding research that was also
- 14 being funded as a CTR special project?
- 15 A. Well again, this would come from the footnote
- 16 credit line of the papers published by the
- 17 investigators where they would acknowledge support by
- 18 CTR as a special project, along with support from one
- 19 or more of these additional institutions and other
- 20 agencies as well.
- 21 MR. WEBER: Your Honor, I'm going to take a
- 22 slight change in topic here, and I can take a break
- 23 whenever the court would want. I just --
- 24 THE COURT: All right. Well let's take a
- 25 short recess now.

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- 1 MR. WEBER: Okay.
- 2 (Recess taken.)
- 3 THE CLERK: All rise. Court is again in
- 4 session.
- 5 (Jury enters the courtroom.)
- 6 THE CLERK: Please be seated.
- 7 MR. WEBER: Thank you, Your Honor.
- 8 BY MR. WEBER:
- 9 Q. Dr. Glenn, last week Mr. Ciresi asked you some
- 10 questions about several specific research projects,
- 11 and I want -- I want to follow up on some of that
- 12 inquiry.
- 13 Do you recall questions about a 1971 proposal to
- 14 fund the research at Washington University --
- 15 A. Yes, sir.
- 16 Q. -- regarding immunological issues and cancer?
- 17 A. Yes.
- 18 Q. Was that ever funded as a CTR special project?
- 19 A. Not according to my record review.
- 20 Q. Was it ever funded as a CTR grant?
- 21 A. Not to my knowledge, no.
- 22 Q. Do you know if it was ever funded in some other
- 23 manner by the companies?
- 24 A. No.
- 25 Q. You have no knowledge one way or the other.

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- 1 A. I do not.
- 2 Q. Mr. Ciresi also asked you some question about

- 3 grants to researchers who were named Spielberger and
- 4 Aviado. Do you remember that?
- 5 A. Yes.
- 6 Q. And he questioned whether CTR might have
- 7 suppressed that research. Do you remember that
- 8 question?
- 9 A. Yes.
- 10 Q. Did CTR fund a researcher named Spielberger with
- 11 a CTR special project?
- 12 A. Not according to our records.
- 13 Q. Did CTR fund a researcher named Spielberger with
- 14 a grant?
- 15 A. No.
- 16 Q. You have no knowledge whatsoever about any
- 17 research performed by Spielberger.
- 18 A. No.
- 19 Q. Did CTR fund Dr. Aviado with a CTR special
- 20 project?
- 21 A. I believe so.
- 22 Q. Do you know if that is the project referred to
- 23 in the document that Mr. Ciresi showed you?
- MR. CIRESI: Objection, Your Honor,
- 25 foundation.

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- 1 THE COURT: Okay. Well you may answer
- 2 that.
- 3 A. Dr. Aviado also was a grantee. I'm not sure
- 4 which is referred to.
- 5 Q. Or whether it's some other project.
- 6 MR. CIRESI: Well, Your Honor, I'm going to
- 7 object to counsel's leading question. There's no
- 8 foundation.
- 9 THE COURT: Yeah, that was leading,
- 10 counsel. Sustained.
- 11 Q. Do you know --
- Do you know what specific project was referred
- 13 to in the document Mr. Ciresi showed you?
- 14 MR. CIRESI: Objection, no foundation. The
- 15 witness has just testified.
- 16 THE COURT: I believe he's answered that,
- 17 counsel.
- 18 BY MR. WEBER:
- 19 Q. With respect to the CTR special project funding
- 20 for Dr. Aviado, could you turn to page -- to tab 23.
- 21 And these are exhibits that are already in evidence,
- 22 MD001143, MD001150. Those are part of the special
- 23 project letters that were admitted earlier.
- 24 A. I have them.
- Q. And let me show you first Exhibit 001143. Do STIREWALT & ASSOCIATES
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- 1 you have that one?
- 2 A. I do.
- 3 Q. January 1978?
- 4 A. Yes, sir.
- 5 Q. And does that talk about Dr. Aviado's right to
- 6 publish in the future, down in the second-to-the-last
- 7 paragraph?

- 8 A. Yes.
- 9 Q. And is this a typical letter to a CTR special
- 10 project recipient?
- 11 A. Yes, it is, similar to the previous letters that
- 12 we reviewed.
- 13 Q. And could you turn to Exhibit 1150, which I
- 14 believe should be next in your tab. Do you see that?
- 15 A. I have it.
- 16 Q. That relates to the same special project number
- 17 93?
- 18 A. Yes, sir.
- 19 Q. Does that also refer to potential future
- 20 publication?
- 21 A. Yes.
- 22 Q. Do you have any information that CTR ever did
- 23 anything to advise Dr. Aviado not to publish?
- 24 A. No.
- Q. Did CTR ever fund projects through device or an STIREWALT & ASSOCIATES
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- 1 account called special account four?
- 2 A. I don't know what special account four is.
- 3 Q. Does CTR have any files that include -- that are
- 4 labeled special account four?
- 5 A. No.
- 6 Q. Did CTR ever fund research through anything
- 7 called lawyers' special projects?
- 8 A. No.
- 9 Q. Does CTR have a file for lawyers' special
- 10 projects?
- 11 A. No, sir.
- 12 Q. To the best of your knowledge, doctor, and
- 13 taking into account your 46 years in academic
- 14 medicine and your work in the research community, do
- 15 you believe that it was unethical or improper for CTR
- 16 to fund research as CTR special projects?
- 17 MR. CIRESI: Objection to the form, no
- 18 foundation, calls for an expert opinion, and also
- 19 calls for an ultimate conclusion of fact by the jury.
- 20 THE COURT: Sustained.
- 21 BY MR. WEBER:
- 22 Q. Based on your knowledge from your review of
- 23 materials, do you believe that CTR did anything
- 24 improper or unethical with respect to funding CTR
- 25 special projects?

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- 1 MR. CIRESI: Same objections, Your Honor.
- 2 THE COURT: Sustained.
- 3 Q. Dr. Glenn, would you turn to Exhibit 11028.
 - It's at tab 24. It's an exhibit already in evidence.
- 5 A. I see that.
- 6 MR. CIRESI: Do you have a exhibit number,
- 7 counsel?
- 8 MR. WEBER: 11028.
- 9 Q. Is that one of the documents that Mr. Ciresi
- 10 showed you last week?
- 11 A. Yes, sir.
- 12 Q. I'd like you to turn to the front page of that.

- 13 Do you know any of these individuals, Bentley, Felton
- 14 or Reid?
- 15 A. No.
- 16 Q. Do you know what their scientific capabilities
- 17 were?
- 18 A. No.
- 19 Q. Is this a document that was in CRT's files?
- 20 A. No
- 21 Q. Had you ever seen this document as part of your
- 22 duties at CTR, apart from litigation?
- 23 A. No, sir.
- 24 Q. Turn to the first page, which is the itinerary.
- 25 You remember Mr. Ciresi asking you some questions STIREWALT & ASSOCIATES
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- 1 about that?
- 2 A. Yes.
- 3 Q. Is --
- 4 At the time was R. J. Reynolds a sponsor; that
- 5 is, in 1958 was R. J. Reynolds a sponsor of TIRC?
- 6 A. Yes, they were.
- 7 Q. Was R. J. Reynolds visited on this trip?
- 8 A. No, sir, not according to this itinerary.
- 9 Q. According to this itinerary was Lorillard
- 10 visited on this trip?
- 11 A. No, sir.
- 12 Q. According to this itinerary was Brown &
- 13 Williamson visited on this trip?
- 14 A. Not according to this itinerary.
- 15 Q. Could you take a look through that document and
- 16 let me know whether it purports to quote directly
- 17 anyone from the CTR?
- 18 A. I've reviewed this document previously, and I
- 19 found no direct quotes from anyone at CTR.
- 20 Q. Are you able to vouch for the accuracy of any of
- 21 the characterizations of conversations in there, sir?
- 22 A. No.
- MR. CIRESI: Excuse me, doctor. That calls
- 24 for speculation. He's already said he's never saw it
- 25 before.

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- 1 THE COURT: No, he can answer the question.
- 2 It's been answered.
- 3 MR. WEBER: He can? He can answer?
- 4 THE COURT: He's already answered.
- 5 MR. WEBER: Okay. I'm sorry, Your Honor.
- 6 BY MR. WEBER:
- 7 Q. Let me ask you this, Dr. Glenn: Could you read
- 8 that bottom paragraph on the page marked 492 from
- 9 this document.
- 10 A. "The SAB," Scientific Advisory Board, "of TIRC
- 11 and the group we at the National Cancer Institute,
- 12 Bethesda, broadly take the view that causation is
- 13 likely to be indirect. Several hypothetical means by
- 14 which this could occur were proposed but with no
- 15 experimental evidence to support any of them."
- 16 Q. All right. And I'd like to go to the next page, 17 493, and ask if you could read that first paragraph

- 18 under "EXTRAPOLATION FROM ANIMAL TESTS TO MAN."
- 19 A. "Without exception no single individual whom we
- 20 met was prepared to extrapolate unambiguously from
- 21 any single animal test to man. At the same time
- 22 there was general agreement that in the field of
- 23 smoking and lung cancer no biological test wholly
- 24 free from criticism is available at the present time
- 25 or is likely to become available in the foreseeable STIREWALT & ASSOCIATES
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- 1 future."
- 2 Q. Now does that express an opinion that you agree
- 3 with, Dr. Glenn?
- 4 A. Yes. I would certainly have agreed at that
- 5 time, 40 years ago, and I -- I think we still have
- 6 the ambiguities.
- 7 Q. Could you go to the page labeled 496.
- 8 A. I have that.
- 9 Q. And start at the paragraph that begins at the
- 10 bottom of the page and goes over to the next page.
- 11 Could you read that paragraph.
- 12 A. "Others, including the Scientific Advisory Board
- 13 of TIRC and a group at the National Cancer Institute,
- 14 do not accept that a case has yet been made that
- 15 tobacco smoke is directly carcinogenic to the human
- 16 lung. While accepting broadly that cigarette smoking
- 17 may be said to be capable of, quote, causing,
- 18 unquote, lung cancer they argue that the evidence
- 19 favors some indirect mechanism of causation. If this
- 20 is so, of course, cancers produced by skin painting,
- 21 and even more so, cell changes produced by short-term
- 22 screening tests are misleading artifacts.
- 23 Unfortunately so long as the basic problems
- 24 underlying the transformation of a normal to a
- 25 cancerous cell remain unsolved, theories of indirect STIREWALT & ASSOCIATES
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- 1 causation must be largely speculative and almost
- 2 without exception incapable of being tested
- 3 experimentally. The advice we had from this group,
- which includes Dr. Little, was that T.M.S.C. should
- 5 concern itself less with direct testing of cigarette
- 6 smoke on animals than with fundamental work on
- 7 carcinogenesis. An idea which we frequently
- 8 encountered was that of an institute financed say by
- 9 T.M.S.C. which would support a number of dedicated
- 10 individuals of proved caliber who would devote their
- time to long range basic research on cancer without being distracted by administrative duties or
- financial worries. No short or medium-term solution
- 14 to the problems facing the industry could be expected
- 15 from such an institution, which would necessarily
- 16 have to have no strings attached, but very long-term
- 17 beneficial results might be expected."
- 18 Q. Could you turn back to page 492, Dr. Glenn, and
- in the paragraph labeled "'CAUSATION' OF LUNG
- 20 CANCER" -- do you see that?
- 21 A. Yes, sir.
- 22 Q. Could you begin reading where it talks about

- 23 Hueper of the National Cancer Institute. Do you see
- 24 that?
- 25 A. Yes, sir.

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- 1 Q. Could you read that.
- 2 A. "Hueper of the National Cancer Institute accepts
- 3 that cigarette smoke is capable of causing lung
- 4 cancer but believes that as compared with other
- 5 environmental carcinogens the contribution of smoking
- 6 to the total mortality from lung cancer is being
- 7 greatly exaggerated."
- 8 Q. Now doctor, turn to page 498, please.
- 9 A. Yes.
- 10 Q. Do you see the second conclusion down there --
- 11 A. Yes.
- 12 Q. -- at the bottom of the page? That hasn't been
- 13 read to the jury yet. Could you read conclusion two.
- 14 A. Conclusion two states: "There remains an area
- of debate to what is meant by, quote, causation, end
- 16 quote. Opinion differs as to whether or not
- 17 cigarette smoke is likely to exert its effect by
- 18 direct action on the lung. An indirect mechanism of
- 19 causation is thought by some to be more likely."
- 20 Q. Now, sir, this was in a 1958 document?
- 21 A. Yes.
- 22 Q. And again, you don't know the authors or the
- 23 accuracy of the report; correct?
- 24 A. No.
- 25 Q. Did you take a look to see what the Scientific STIREWALT & ASSOCIATES
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- 1 Advisory Board itself said in this same period about
- 2 the issue of causation?
- 3 A. I think they were saying the same things, that
- 4 there were real questions as to whether there was a

Q. Did you look at the minutes of the Scientific

- 5 direct effect on the lung of cigarette smoking.
- 7 Advisory Board --
- 8 A. I did.

6

- 9 Q. -- to -- to determine what the Scientific
- 10 Advisory Board itself said about this issue of
- 11 causation?
- 12 A. Yes.
- 13 Q. Could you turn to the Scientific Advisory Board
- 14 minutes, which is Exhibit MD001258, I believe. Those
- 15 should be in a separate binder up there. They were
- 16 admitted into evidence already.
- 17 A. Tell me the number again, please, sir.
- 18 Q. It's Exhibit MD001258. Those are the minutes of
- 19 the Scientific Advisory Board.
- 20 A. Yes.
- 21 Q. May I approach --
- 22 A. I have those.
- 23 Q. Okay. And could you turn to the page that is
- 24 Bates stamped at the bottom 153.
- 25 A. What would be the date on that?

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- It would be March 10, 1960, and the page -- the 1
- stamp at the bottom of the page would be 153, Dr.
- 3
- I go from 152 to 154. I can read the --Α. 4
- Do we have a copy of that? 5
- 6 Well let me ask you to identify this as page
- 7 153, on the screen.
- 8 A. Yes.
- 9 Ο. And is this the cover sheet to a meeting of the
- Scientific Advisory Board in March 10 and 11 of 1960? 10
- 11 It is.
- 12 Do you have page 157 there, Dr. Glenn? Q.
- 13 Α. Yes.
- 14 Q. And is 157 a report by the Scientific Advisory
- 15 Board to the TIRC?
- 16 A. Yes.
- 17 Q. And that was part of the minutes of that
- 18 meeting?
- 19 Α. Yes.
- 20 Ο. I'd like you to turn to the next page, 158. Do
- 21 you have that, sir?
- A. I do. 22
- 23 Q. And ask you to turn to the paragraph that begins
- 24 "Even though...."
- 25 Α. Yes.

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- And to read that portion of the report of the 1
- Scientific Advisory Board in 1960.
- "Even though it must be admitted that the effort
- thus far has barely scratched the surface, excellent 4
- scientific studies have been reported, and it can 5
- confidently be assumed that the facts revealed will
- 7 ultimately contribute to the solution of the broad
- questions which concern us. But perhaps the most 8
- 9 significant development has been the general
- recognition that we do not yet have the answer; that 10
- an association between the extent of tobacco use and 11
- the incidence of lung cancer does not prove a causal 12
- 13 relationship, that experimental verification is
- 14 essential and that there are a number of other
- 15 factors which need to be considered. Today, instead
- of letting the problem rest with the statement that 16
- 17 to smoke in excess of two packs of cigarettes per day
- 18 results in a ten-fold increase in the risk of cancer,
- 19 there is general interest in the 90 percent of heavy
- 20 smokers who escape the disease despite heavy smoking.
- 21 We are also vitally interested in the meaning of the
- results, derived from the same data, that only a 23 small fraction of the reported excess deaths in the
- 24 heavy smoking group is attributable to cancer of the
- 25 lungs."

22

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- 1 Dr. Glenn, from your standpoint, if one wanted
- to find out the view of the Scientific Advisory Board
- on the question of causation, is it a more reliable

- 4 source to look to the Scientific Advisory Board's own
- 5 report, or to look to a report from some British
- 6 people?
- 7 MR. CIRESI: Object to the form of the
- 8 question, Your Honor.
- 9 THE COURT: Sustained.
- 10 Q. This is the SAB's own words in 1960; correct?
- 11 A. Yes, sir.
- 12 Q. Could you turn to Exhibit 11027, Dr. Glenn,
- 13 which is at tab 25.
- 14 A. I have that.
- 15 Q. And is this a --
- 16 Is Exhibit 11027 one of the plaintiffs' exhibits
- 17 that Mr. Ciresi showed you the other day?
- 18 A. Yes, it is.
- 19 Q. Had you ever seen this, apart from litigation?
- 20 A. Only in connection with litigation.
- 21 Q. Is this document in CRT's files?
- 22 A. No, sir.
- 23 Q. Who's the author of this document, can you tell?
- 24 A. I can't tell. I -- it's --
- 25 Having looked at it previously, I couldn't tell STIREWALT & ASSOCIATES
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- 1 who wrote it.
- 2 Q. Is there a signature or a name listed on it
- 3 anywhere?
- 4 A. No, sir.
- 5 Q. Are there any direct quotes here from the CTR?
- 6 A. No, sir.
- 7 Q. Could you turn to the page -- and I'll just give
- 8 you the last three numbers of the Bates stamp in the
- 9 lower right corner, Dr. Glenn, because the pages
- 10 aren't otherwise numbered -- page 269.
- 11 A. Yes, sir.
- 12 Q. And I'd like to direct your attention to the
- 13 first full paragraph at the top of the page.
- 14 A. Yes, sir.
- 15 Q. And this is referring to --
- This purports to be a report on a conversation
- 17 with Dr. Wakeham.
- 18 A. Yes.
- 19 Q. Can you read what that says?
- 20 A. "Wakeham said that polycyclics were effective in
- 21 contributing to cancer in mouse skin painting, but
- 22 the quantities in smoke were too small to be
- 23 significant, as the Surgeon General Advisory
- 24 Committee report had stated."
- 25 Q. Now that says "SGAC," but that refers to Surgeon STIREWALT & ASSOCIATES
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- 1 General's Advisory Committee; correct?
- 2 A. Yes.
- 3 Q. And is that the point you made last Friday in
- 4 your testimony?
- 5 A. Yes.
- 6 Q. Could you turn to the page labeled 290, Dr.
- 7 Glenn
- 8 A. Yes, I have that.

- And does this purport to be a report of a
- meeting with Dr. M. H. Seevers? 10
- 11 A. It is labeled "Discussion with Dr. M. H.
- Seevers, Ann Arbor, Michigan, October 1, 1964." 12
- Q. Did Dr. Seevers have any involvement with the 13
- 14 Surgeon General's Advisory Committee in 1964?
- A. Dr. Seevers was the chairman of the Surgeon 15
- 16 General's Advisory Committee.
- 17 Q. He was a member of that committee; correct?
- A. Yes. 18
- Q. Let me just show from the 1964 report a list of 19
- 20 the members here. That lists Dr. Seevers at the
- bottom; correct? 2.1
- 22 A. Correct.
- Now this document in front of you purports to 23 Q.
- 24 reflect a discussion with Dr. Seevers in October '64?
- 25 A. Yes, sir.

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- Q. And that's about 10 months after the issuance of
- the Surgeon General's report? 2
- 3 A. Yes.
- I'd like you to start reading about AMA research 4 Q.
 - into smoking and health there, and I'll have a few
- 6 questions as we go along, Dr. Glenn.
- A. "To date, the committee (of which Seevers is 7
- chairman) appointed by the Education and Research 8
- 9 Foundation of the AMA to direct the programs for
- 10 using the 10-million-dollar fund contributed by the
- 11 U.S. cigarette manufacturers, has approved 28 grants.
- 12 The total cost of these over the periods for which
- they have been approved will be \$2,400,000. Details 13
- of the grants are attached." 14
- 15 Q. Okay.
- "The main considerations" --16 Α.
- 17
- Q. Continue, please.A. "The main considerations which have been in the 18
- 19 minds of the Seevers committee in making these grants
- 20 have been:

5

6 7

- 21 "(1) It is necessary to get more good people to
- 22 undertake research in the smoking and health field,
- whether or not they live in the U.S. 23
- "(2) Research into cancer is not excluded but 2.4
- 25 it has been over-supported in relation to other STIREWALT & ASSOCIATES
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- aspects. Under-supported have been research into
- respiratory disease, cardiovascular disease, cellular 2
- studies, ciliary activity, pharmacological and 3
- psycological reasons for smoking.
 - "(3) It is particularly necessary to find means of determining nicotine in the blood and organizing a supply of radio-active nicotine. The Committee aim
- 8 particularly at developing techniques. 9 "(4) The Committee do not plan to build their 10 own laboratory though they may use the general
- 11 medical research laboratory being built for the ERF
- 12 of AMA in Chicago.
- 13 "Where gaps exist, the Committee will initiate

- research projects to close them. They already have two or three such projects.
- 16 "(6) The Committee is not concerned with
- 17 modifications to cigarettes, how to treat tobacco et
- 18 cetera. The manufacturers are more competent to do
- 19 this. Similarly, the Committee is not concerned with
- 20 cigarette tars, which would require a laboratory for 21 their production.
- "(7) The House of Delegates of the AMA, in
- 23 accepting the fund, looked to it being used for the
- 24 development of safe cigarettes. The Committee
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- had no manufacturing competence, et cetera Seevers
 said they had a hard time getting away from this
- 3 objective.
 4 "(8)
 - "(8) The Committee would support
- 5 epidemiological studies if they received good6 applications.
- 7 "(9) The Committee may support research in more 8 fields as they get more and more projects going.
- 9 "(10) They may add other experts (an example, 10 pathologists) to the Committee; just feeling their 11 way at present.
- "(11) If they find good projects, they won't
- hesitate to spend over the 10 million dollars as the AMA would have no difficulty in finding more money.
- 15 "(12) They have refused to finance anti-smoking 16 clinics or education.
- 17 "(13) They expect to co-operate closely with
- 19 Q. Let me stop you there for a moment, Dr. Glenn.
- 20 This refers to a 10-million-dollar grant given by the
- 21 cigarette manufacturers to the AMA?
- 22 A. Yes, sir.
- 23 Q. And the AMA set up a board of scientific
- 24 advisors to approve research applications?
- 25 A. Yes.

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- 1 Q. Were you one of the researchers back in those
- $2\,$ days who received a grant from the AMA pursuant to
- 3 this?
- 4 A. My laboratory -- my laboratory, the laboratory
- 5 under my direction, received a grant for study under
- 6 the American Medical Association Education and
- 7 Research Fund.
- 8 Q. Would you go to the next page, Dr. Glenn, where
- 9 it reports -- the page that begins "Seevers' personal
- 10 views...."
- 11 A. Yes, sir.
- 12 Q. Now again, Dr. Seevers had been on the Surgeon
- 13 General's committee that had issued the report 10
- 14 months earlier; correct?
- 15 A. Correct.
- 16 Q. What does this say about Dr. Seevers' personal
- 17 views?
- 18 A. "1. Seevers does not believe that it has been

- 19 proved that smoking causes lung cancer. There is an
- 20 association and it should be made known. The
- 21 strongest evidence for a causal connection is
- 22 Auerbach's work, but it is not conclusive. Seevers
- 23 is not sure the validity of the statistics."
- 24 Q. The next --
- 25 Could you read the next paragraph as well. STIREWALT & ASSOCIATES
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- A. "2. Seevers is convinced the main reason why
- 2 people smoke is the nicotine. He thinks it important
- 3 to keep the nicotine content up. He has suggested to
- 4 Hanmer of The American Tobacco Company that they
- 5 should add back nicotine to cut the tobacco and then
- 6 reduce both nicotine and tar, as in Carlton, by
- 7 filter and porous paper. To produce a non-tobacco
- 8 cigarette was contrary to common sense."
- 9 Q. Could you go now, Dr. Glenn, to the page 294.
- 10 A. Yes, sir.
- 11 Q. And this continues the purported
- 12 characterization of the discussions with Dr. Seevers;
- 13 correct?
- 14 A. Yes.
- 15 Q. What does this say about the Surgeon General's
- 16 Advisory Committee?
- 17 A. "Seevers said that it was a committee of prima
- 18 donnas. Although none of the members had published
- 19 expressed views on smoking and health they all had
- 20 very definite views. The Surgeon General never came
- 21 near the committee. Handley acted as chairman of the
- 22 meetings; he was pleasant but ineffective, allowing
- 23 far too much irrelevant chat. Bains-Jones, as oldest
- 24 member, had to step in from time to time to get
- 25 points settled. Two whole days were spent discussing STIREWALT & ASSOCIATES
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- the meaning of, quote, cause, unquote. The political
- 2 people tried to hurry up the committee but did not
- 3 otherwise try to influence them. The, quote, member
- 4 responsible for cancer (probably Furth) submitted a
- 5 draft for the chapter on cancer that had been written
- 6 by the American Cancer Society. This was thrown
- 7 out."
- 8 Q. Now, do you remember the earlier trip report
- 9 that we discussed, I think that was Exhibit 11028
- 10 from 1958, and it talked about how there was a debate
- 11 as to what the meaning of "cause" was. Do you
- 12 remember that?
- 13 A. Yes.
- 14 Q. And here we see that Dr. Seevers in October
- 15 1964, according to this document, did not believe
- 16 that it had been proven that smoking caused cancer;
- 17 correct?
- 18 A. Yes.
- 19 Q. And Dr. Seevers, again according to this
- document, says that two whole days were spent by the
- 21 Surgeon General's committee discussing the meaning of
- 22 "cause." Do you see that?
- 23 A. Yes.

- 24 Q. I'd like to turn you now to the 1964 Surgeon
- 25 General's report, Dr. Glenn. What tab is that? I STIREWALT & ASSOCIATES
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- think it's tab 43, MD000102. That's already in
- 2 evidence.
- 3 A. I have that.
- 4 Q. And could you turn to page 21 then.
- 5 A. I have that.
- 6 Q. And could you turn to paragraph four, paragraph
- 7 number four in the causality section.
- 8 A. Yes.
- 9 Q. And this is where, in the introduction, they're
- 10 discussing causality; correct?
- 11 A. Yes.
- 12 Q. All right. Can you read that to the jury.
- 13 A. "It should be said at once, however, that no
- 14 member of this committee used the word 'cause' in an
- 15 absolute sense in the area of this study. Although
- 16 various disciplines and fields of scientific
- 17 knowledge were represented among the membership, all
- 18 members shared a common conception of the multiple
- 19 etiology of biological processes."
- 20 Q. Let me stop you there. What does "multiple
- 21 etiology" mean, Dr. Glenn?
- 22 A. Means that there may be many, many factors
- 23 involved in the genesis of any particular condition,
- 24 whether it be cancer or other disease.
- 25 Q. You mean "etiology" means cause? STIREWALT & ASSOCIATES
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- 1 A. Means causes.
- 2 Q. So this means --
- 3 This says everyone agreed that there were many 4 causes.
- 5 A. Yes.
- 6 Q. Would you continue.
- 7 A. "No member was so naive as to insist upon
- 8 mono-etiology in pathologic processes or in vital
- 9 phenomena. All were thoroughly aware of the fact
- 10 that there are series of events in occurrences and
- 11 developments in these fields, and that the end
- 12 results are the net effect of many actions and
- 13 counteractions."
- 14 Q. Now, Dr. Glenn, does the fact that "cause" was
- 15 not used in an absolute sense, the fact that there
- 16 was a common conception of multiple etiology, and
- 17 that no one was so naive as to insist upon
- 18 mono-etiology, would you explain how those ideas
- 19 relate to your statements the other day about the
- 20 importance of defining "cause?"
- 21 MR. CIRESI: Objection to the form of the
- 22 question, Your Honor. It's a multiple question.
- 23 It's also impeaching his own witness.
- 24 MR. WEBER: I object and move to strike
- 25 that comment, Your Honor. It's entirely

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- 1 inappropriate.
- 2 MR. CIRESI: It's an inappropriate
- 3 objection, impeaching their own witness.
- 4 THE COURT: Okay. You'll have to rephrase
- 5 your question, counsel.
- 6 BY MR. WEBER:
- 7 Q. Dr. Glenn, taking into account Exhibit 1127 that
- 8 talked about a definition of "cause "-- you remember
- 9 that?
- 10 A. Yes, sir.
- 11 O. -- and 1128, where we saw Dr. Seevers' personal
- 12 views as reported in that document -- correct?
- 13 A. Yes, sir.
- 14 Q. -- and taking into account this paragraph four,
- 15 do those documents along with your learning relate in
- 16 any way to the need to agree upon a definition of
- 17 "cause" when discussing chronic disease?
- 18 A. Yes.
- 19 Q. Could you explain that.
- 20 A. Well I -- I don't know that there's any simple
- 21 explanation. We have said that in order to establish
- 22 cause, it should be -- it should have some
- 23 universality, that we ought be able to reproduce
- 24 results. Here in this document and in the others
- 25 that we've looked at it is clear that scientists even STIREWALT & ASSOCIATES
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- 1 30, 40 years ago were worrying about the same
- 2 questions. This has led to the -- to the recognition
- 3 that there are multiple risk factors involved in a
- 4 number of diseases. And to digress from lung cancer,
- 5 you can take, for example, arteriosclerosis. We know
- 6 that diet plays a role, the level of your
- 7 cholesterol, we know that activity plays a role, we
- 8 know that hormones play a role, so there are multiple
- 9 causes of arteriosclerosis. The same thing can be
- 10 said of virtually every disease, that there are a
- number of factors that are involved. We probably
 have only just seen the tip of the iceberg, but as
- have only just seen the tip of the iceberg, but at least we've come to the recognition that there are
- 14 fundamental problems.
- And the thing that the scientific community has
- 16 done most effectively, I think, is to -- is to
- 17 recognize that there are marked individual
- 18 differences which may underlie everything. These
- 19 individual differences are genetics. Probably the
- 20 best thing we can do to avoid disease is to pick the
- 21 right parents, because our -- our -- our inheritance,
- 22 our genetic makeup --
- MR. CIRESI: Your Honor, we're going beyond
- 24 the scope of this witness's examination.
- 25 Q. All right, Dr. Glenn, let me move to a different STIREWALT & ASSOCIATES
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- 1 topic now.
- 2 Has CTR, to your knowledge, been represented by
- 3 counsel since its inception?
- 4 A. Yes.

```
Q. Why does a research organization, in your mind,
    need to be represented by counsel?
 6
7
              MR. CIRESI: Objection, Your Honor, it's
8
     vague and overbroad.
              THE COURT: I'm not sure that it's
9
    relevant, counsel.
10
              MR. WEBER: The relevance is, if you'll
11
    give me a few questions, I'll make -- make it clear
12
13
    because I'm leading up to a specific situation, Your
14
    Honor.
15
              THE COURT: Okay.
    BY MR. WEBER:
16
    Q. Can you explain why a research organization,
17
18
    based on your experience, needs to be represented by
19
    counsel?
2.0
    A. I think there are a variety of reasons. Any
    research organization, any university I've ever been
2.1
    associated with, any hospital, has counsel, because
2.2
23
    you enter into contracts for research, you -- you
24
    subscribe to certain conditions of a grant, you have
25
    fiscal responsibility, responsibility for the money
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    that's involved. There are always antitrust issues,
    for example, in an organization such as the CTR.
              MR. CIRESI: Excuse me, Your Honor. We're
 3
    now well beyond what this gentleman is here for.
 4
 5
              THE COURT: We aren't going to get into his
    version of antitrust issues.
 6
7
             MR. WEBER: Not his version of law, but in
8
    specific situations I want to get into, Your Honor.
    Q. Based on your experience at CTR and the fact
9
    that it's sponsored by companies, independent
10
    companies in the marketplace, has CTR received advice
11
12
    on antitrust issues from time to time?
    A.
13
        Now without revealing any of the substance of
14
    Q.
15
    that advice, are you aware of a situation back in the
    1970s when the Scientific Advisory Board received
17
    advice on antitrust issues?
              MR. CIRESI: Your Honor, if he's going to
18
19
    testify to this, it opens up the subject, and we will
2.0
    be entitled to the documentation regarding it, which
21
    has been resisted.
22
              THE COURT: Counsel, I suggest you use
23
    extreme care.
24
              MR. WEBER: May I be heard at side bar on
25
    this, Your Honor.
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 1
              THE COURT: Yes, you may.
 2
 3
 4
 5
 6
 7
 8
 9
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10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	STIREWALT & ASSOCIATES
	P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1953 DIRECT EXAMINATION - JAMES F. GLENN 4870
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	(Side-bar conference as follows:) STIREWALT & ASSOCIATES
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1 2 3 4 5 6 7 8 9 10 11 12 13	4871

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11
               (Side-bar conference concluded.)
12
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 1
    BY MR. WEBER:
 2.
   Q. Let's talk for a minute, Dr. Glenn, about the
    scope of the SAB research program and its relevance
 3
    to the purpose of The Council for Tobacco Research.
    All right?
 5
          First of all let me ask you: Have the companies
 6
 7
    ever told you that CRT's Scientific Advisory Board
    should avoid certain areas of research?
 8
9
    A. No, sir.
10
    Q.
         Now do you recall Mr. Ciresi asked some
    questions last week about criticisms of CTR by
12
    scientists in the various sponsor companies in the
13
    sixties and seventies?
14
    A. Yes.
15
    Q. Do you recall that some of those documents
16
    suggested that CTR should be redirected or
17
   restructured?
18
    A. Yes.
19
     Q. That company scientists should be put on its
```

- 20 board?
- 21 A. Yes.
- 22 Q. That CTR should be made more directly useful to
- 23 the industry?
- 24 A. Yes.
- Q. Was CTR so restructured, Dr. Glenn? STIREWALT & ASSOCIATES
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- 1 A. No, sir.
- 2 Q. Were company scientists put in control of CTR?
- 3 A. No, sir.
- 4 Q. Was the role of the Scientific Advisory Board
- 5 changed because of these internal criticisms?
- 6 A. No.
- 7 Q. Was it part of CRT's charter to do research that
- 8 the companies' scientists would find useful or
- 9 helpful?
- 10 A. No.
- 11 Q. Do you believe that CRT's grant program over the
- 12 years has been relevant to its charter, the
- 13 investigation of diseases and disease processes
- 14 associated with smoking?
- 15 A. Progressively so.
- 16 Q. Does the fact that many of these projects don't
- 17 specifically say they relate to tobacco or smoking
- 18 make that research irrelevant?
- 19 A. No, sir.
- 20 Q. What I'd like you to -- to do for us is
- 21 explain --
- Well before I get to it, let me ask this: Has
- 23 the type of research focused on by the Scientific
- 24 Advisory Board changed over the years based on your
- 25 knowledge of the research that's been funded? STIREWALT & ASSOCIATES
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- 1 A. Yes, very much so.
- 2 Q. Can you explain that?
- 3 A. Well I think the best explanation is that
- 4 there's been an evolution of scientific thought. If
- 5 you go back historically and look at the very first
- 6 medical investigations five hundred years ago, they
- 7 were anatomic. The scientists of the time were
- 8 looking at gross human anatomy. Later on they began
- 9 to focus on abnormal anatomy and diseased organs, but
- 10 they were still looking at things grossly. It was
- 11 not until the advent of the microscope that they were
- 12 able to take a microscopic look at things.
- 13 In more modern times it's been obvious that if
- 14 we're going to understand fundamental disease we've
- 15 got to know what happens within individual cells,
- 16 what happens to individual molecules, and
- 17 specifically why those cells and molecules go wrong,
- 18 which is most probably related to immunology and
- 19 genetics. So the focus of research has become more
- 20 and more precise, more and more defined. The same
- 21 thing has happened to research sponsored by CTR
- 22 that's happened in the general scientific community,
- and that is that we're focusing more and more on
- 24 these fundamental processes.

- 25 In the beginning, if you look back historically STIREWALT & ASSOCIATES
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- 1 at the CTR documents, the early studies were
- 2 epidemiological, relating smoking to diseases. There
- were studies of smoke inhalation in animals, exposing
- 4 animals to cigarette smoke. They were very broad in
- 5 their implication, but it didn't say anything to why
- 6 does the -- this -- this cause an abnormality. So I
- 7 think the Scientific Advisory Board exhibited
- 8 tremendous insight as they began to focus their
- 9 research on the more molecular levels, the cellular
- 10 levels, and in recent years the genetic level. This
- 11 has been in parallel to what's been happening at the
- 12 federal level.
- 13 I'm sure you know -- all know that one of the
- 14 biggest scientific projects facing the country today
- is the so-called human genome project. What
- 16 they're -- what the NIH is attempting to do --
- 17 MR. CIRESI: Your Honor, this is -- this is
- 18 well beyond the scope of this individual's testimony.
- 19 Q. Let me ask -- let me ask you this: Is CTR
- 20 funding work in genetics?
- 21 A. Yes, sir.
- 22 Q. Immunology?
- 23 A. Yes, sir.
- 24 Q. Molecular biology?
- 25 A. Yes, sir.

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- 1 Q. Microbiology?
- 2 A. Yes, sir.
- 3 Q. Virology?
- 4 A. Yes, sir.
- 5 Q. Are all of those fields relevant to the
- 6 questions you're looking at?
- 7 A. Absolutely.
- 8 Q. Has the National Institute of Health been
- 9 criticized for undertaking basic research of this
- 10 type into diseases as well?
- MR. CIRESI: Your Honor, objection, it's
- 12 totally irrelevant to this case.
- 13 THE COURT: You can answer that.
- 14 A. Yes. There has been criticism that the NIH was
- 15 not focused on broad aspects of disease but more on
- 16 basic science, and as a matter of fact, the director
- 17 of NIH has defended this vigorously.
- 18 Q. That is to say, he's defended doing this
- 19 molecular basic research.
- 20 A. Yes.
- 21 Q. Now last week Mr. Ciresi asked you a question
- 22 based on some of your congressional testimony. Do
- 23 you remember that?
- 24 A. Yes.
- 25 Q. And you stated that he wasn't focusing on all of STIREWALT & ASSOCIATES
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- 1 your congressional testimony. Remember that?
- 2 A. Yes, sir.
- 3 Q. Is the explanation of relevance that you've just
- 4 given consistent with that testimony?
- 5 A. Yes, it is.
- 6 Q. Has CTR research made real and substantial
- 7 contributions to understanding diseases and disease
- 8 processes associated with smoking?
 - MR. CIRESI: Objection, calls for
- speculation, conclusion, expert opinion. He's not qualified.
- 12 THE COURT: Sustained.
- 13 Q. You've been scientific director of CTR?
- 14 A. Yes, I have.
- 15 Q. You've been a member of the Scientific Advisory
- 16 Board of CTR?
- 17 A. Yes, I have.
- 18 Q. And on the Scientific Advisory Board you've met
- 19 with leading scientists in areas from throughout this
- 20 country?

- 21 A. Yes, sir.
- 22 Q. Do you know whether the Scientific Advisory
- 23 Board of CTR believes that its research has made
- 24 substantial contributions to understanding the
- 25 diseases associated with smoking and health? STIREWALT & ASSOCIATES
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- 1 MR. CIRESI: Well, same objections, and
- 2 also calls for hearsay, speculation, conjecture.
- 3 THE COURT: Well it's --
- 4 MR. WEBER: It's a verbal act, Your Honor,
- 5 and it's obviously what they've done as an
- 6 organization.
- 7 THE COURT: Yeah. It's pretty
- 8 self-serving. I think we should move on.
- 9 BY MR. WEBER:
- 10 Q. How do you rate the overall quality of CRT's
- 11 research funded through the SAB, Dr. Glenn?
- 12 A. I think it's outstanding.
- MR. CIRESI: Your Honor -- excuse me,
- 14 doctor, excuse me. Same objection, he's not been
- 15 offered on this.
- 16 THE COURT: Okay. I'll -- I'll allow him
- 17 to give his rating.
- 18 A. I think that the track record of the SAB in
- 19 selecting research projects has been absolutely
- 20 outstanding.
- 21 Q. Let me ask you, Dr. Glenn, to turn to Exhibit
- 22 1949, which should be in tab 28. And that's a
- 23 demonstrative exhibit.
- 24 A. I have it.
- 25 Q. Is that a demonstrative exhibit that relates to STIREWALT & ASSOCIATES
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- 1 what the Frank Statement said about the TIRC?
- 2 A. Yes.
- 3 MR. WEBER: Your Honor, I'd move the
- 4 introduction of Exhibit 1949 for demonstrative
- 5 purposes.

```
MR. CIRESI: I have no objection to this.
 6
7
              THE COURT: Court will receive 1949 for
8 demonstrative purposes.
9 BY MR. WEBER:
10 Q. And again, this might be a little more legible
11
    on these side monitors than on -- on the big one.
        Now this exhibit talks about what the Frank
12
13
    Statement said about the TIRC or CTR itself; correct?
14
    A. Correct.
15
    Ο.
         And that portion about the TIRC is highlighted
16
    over there on the right.
17
18
        Now it says that the companies are pledging aid
    Q.
19
    and assistance to the research effort. Do you see
20
    that?
2.1
    A. I do.
22
   Q. Did that happen?
23
   A. Yes, sir, it did.
24 Q. It said it was establishing a joint industry
25 group consisting of the undersigned known as the
                   STIREWALT & ASSOCIATES
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                                                  4881
    TIRC. Did that happen?
 1
    A. Yes, sir.
         It said that in charge of the research
 3
    activities would be a scientist of unimpeachable
    integrity and national repute. Did that happen?
 5
 6
    A. Very definitely.
    Q. And who was that scientist?
 7
   A. Dr. C. C. Little.
 8
   Q. It also said there would be an Advisory Board of
9
    scientists disinterested in the cigarette industry.
10
    "A group of distinguished men from medicine, science
11
12
    and education will be invited to serve on this board.
13
    These scientists will advise the committee on its
14
    research activities." Did that happen?
15 A. Yes, sir.
16 Q.
        Has there been a Scientific Advisory Board
17
    throughout the years for CTR?
18 A. There has.
        Are you proud of the work you've done for CTR,
    Q.
19
    Dr. Glenn?
20
2.1
    A. Absolutely.
2.2
    Q. If the grants that CTR through its SAB makes
23
    weren't supported by money from cigarette companies,
24
    do you think anybody would be complaining about these
25
    grants?
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 1
              MR. CIRESI: Your Honor, objection to the
    form of the question.
              THE COURT: Sustained.
 3
              MR. WEBER: That's all I have, Your Honor.
 4
 5
    I've got to move a few things though.
                       RECROSS-EXAMINATION
 6
 7
    BY MR. CIRESI:
   Q. Good morning, doctor.
 8
 9
   A. Good morning, Mr. Ciresi.
10 Q. When the Frank Statement was put up there, Mr.
```

- 11 Weber quit reading after the fact pledging aid and
- 12 assistance to the research effort, but then he
- 13 stopped; didn't he?
- 14 A. I don't remember.
- 15 Q. You don't remember. Well let me read the rest
- of that statement, "research effort into all phases
- of tobacco use and health." That was the pledge;
- 18 correct?
- 19 A. Yes.
- 20 Q. Okay. Now today you talked about a number of
- 21 studies that were done; correct?
- 22 A. Yes.
- 23 Q. Ones that were done here in Minnesota.
- 24 A. Yes.
- 25 Q. Tell me which one of those studies dealt STIREWALT & ASSOCIATES
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- directly with smoking and health and what was the
- 2 protocol for that study.
- B A. I think they all dealt with smoking and health,
- 4 because we have to understand the basic disease
- 5 process.
- 6 Q. That's not what I asked, sir. Tell me which one
 - of those studies felt -- or dealt specifically with
- $8\,$ $\,$ smoking and health and what was the protocol for that
- 9 study.

7

- 10 MR. WEBER: Objection, Your Honor, it was
- 11 asked and answered.
- 12 THE COURT: It hasn't been answered. You
- may answer.
- 14 A. All of them.
- 15 Q. Sir, tell me the protocol for one of the studies
- 16 that dealt specifically with smoking and health.
- 17 Tell me the protocol.
- 18 A. I can't -- I can't tell you the protocol.
- 19 Q. You can't tell me the protocol for any of those
- 20 studies; can you, sir?
- 21 A. No. No.
- 22 Q. You can't tell us the protocol for any of the
- 23 studies conducted by the entire funding of the CTR
- over its 40 years; can you?
- 25 A. That's true, because the protocol is a STIREWALT & ASSOCIATES
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- scientific document and I can't repeat that to you.
- 2 Q. So you can't tell us specifically how any of
- B those studies, if any of them, dealt specifically
- 4 with smoking and health; can you, as you sit here?
- 5 A. Yes.
- 6 Q. Sir, then tell me one protocol of one study.
- 7 A. I can't tell you the protocol. I can tell you
- 8 that understanding basic disease process is
- 9 fundamental to unlocking the problem of smoking and
- 10 health.
- 11 Q. I didn't ask you about the general basic disease
- 12 process, I asked about smoking and health.
- MR. WEBER: Object to the --
- 14 Q. A specific -- excuse me. A specific protocol
- 15 for smoking and health, can you describe it?

- 16 A. No.
- 17 MR. WEBER: Object to the introduction
- 18 and -- and the commenting, Your Honor.
- 19 THE COURT: Okay. Try and avoid comment,
- 20 counsel.
- 21 Q. Is your answer no, sir?
- 22 A. No.
- 23 Q. Thank you.
- Now you talked about the members of the SAB;
- 25 correct?

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- 1 A. Yes.
- 2 Q. And how many of those personally have you known
- 3 over the years?
- 4 A. Well we'd have to look at the list. I don't --
- 5 I did not personally know people who were on the
- 6 Scientific Advisory Board from 1954, but I have known
- 7 many of them over the years. All of the current
- 8 members are well known to me and many of the former
- 9 members.
- 10 Q. All right. So you've known a number. Would
- 11 that be a fair statement?
- 12 A. I'm sorry?
- 13 Q. You have known a number of them. Would that be
- 14 a fair statement?
- 15 A. Yes.
- 16 Q. Okay. And you said that all of the members were
- 17 of quality; correct?
- 18 A. Yes.
- 19 Q. Of integrity; correct?
- 20 A. Yes.
- 21 Q. Cream of the crop, isn't that what you said?
- 22 A. Yes.
- 23 Q. Some were members of the National Academy of
- 24 Sciences; correct?
- 25 A. Yes.

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- 1 Q. Some were Nobel Prize winners. I think you
- 2 mentioned three; correct?
- 3 A. Those were grantees.
- 4 Q. Grantees. Is that right?
- 5 A. Yes.
- 6 Q. Now when did the CTR survey all of those
- 7 individuals to determine their opinions whether
- 8 smoking caused lung cancer?
- 9 A. Never.
- 10 Q. When did they survey all of those individuals to
- 11 determine whether or not smoking caused COPD?
- 12 A. Never.
- 13 Q. When did the CTR survey all of those eminent
- 14 scientists with respect to whether or not smoking
- 15 caused heart disease?
- 16 A. Never.
- 17 Q. When did the CTR survey all of those eminent
- 18 scientists to determine whether they felt smoking
- 19 caused oral cancer?
- 20 A. Never.

- 21 Q. When did CTR survey all of those eminent
- 22 scientists to determine whether they felt smoking
- 23 caused laryngeal cancer?
- 24 A. Never.
- 25 Q. When did the CTR survey all of those eminent STIREWALT & ASSOCIATES
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- 1 scientists to determine whether or not smoking caused
- 2 esophageal cancer?
- 3 A. Never.

1.0

- 4 Q. When did the CTR survey all of those eminent
- 5 scientists to determine whether or not they believed
- 6 smoking caused kidney cancer?
- 7 A. Never. But --
- 8 Q. When did the CTR --
- 9 A. -- you have to ask --
 - You have to let me finish my answer, Mr. Ciresi.
- 11 Q. Sir, I only asked whether they surveyed or not,
- 12 and your answer is no; correct? Is that correct?
- 13 A. My answer is no. But there is no point in a
- 14 survey. A survey is not a scientific document. And
- 15 every eminent scientist that you have alluded to
- 16 certainly had his own opinions about causation and
- 17 what causation constitutes, and certainly had his own
- 18 information about the statistical relationship of
- 19 smoking and other activities to the risk of
- 20 developing certain diseases, so a survey would have
- 21 been naive to say the least and unfortunate at best.
- 22 Q. I understand you like the word "naive," sir.
- 23 You've used that before; haven't you?
- MR. WEBER: Objection to the commentary,
- 25 Your Honor.

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- 1 Q. Well let me just ask the question very simply.
- 2 MR. WEBER: Can I move to strike that?
- 3 THE COURT: Counsel --
- 4 MR. CIRESI: I'll withdraw it.
- 5 THE COURT: Withdraw it. All right.
- 6 Q. You've used the word "naive" before; correct?
- 7 A. Yes.
- 8 Q. Now, when did the CTR survey all of their
- 9 eminent scientists as to whether or not smoking
- 10 caused bladder cancer?
- 11 A. Never.
- 12 Q. When did the CTR survey all of their eminent
- 13 scientists to determine whether or not smoking caused
- 14 pancreatic -- pancreatic cancer?
- 15 A. Never.
- 16 Q. When did the officials, the executive officers
- 17 of the defendant manufacturing companies, come to the
- 18 CTR and say, "We think there's a controversy. Let's
- 19 get these eminent scientists in and we, the CEOs of
- 20 the company, want to hear what they say?" When did
- 21 they do that?
- 22 A. Never.
- 23 Q. When did the CEOs of any of these companies ever
- 24 say, "Please go out to these eminent scientists and
- 25 find out whether they believe, based on all of their

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- 1 research, that smoking causes any of the diseases
- 2 that I just asked you about?" When did they do that,
- 3 sir?
- 4 A. Never, because the term "causation" was
- 5 inappropriate.
- 6 Q. We'll get to that, sir.
- 7 MR. WEBER: Object to that again, and move
- 8 to strike it, Your Honor.
- 9 MR. CIRESI: Well, Your Honor, that
- 10 wasn't --
- 11 MR. WEBER: It's continuing.
- 12 THE COURT: I'll allow that comment.
- 13 Q. When did the CEOs of any of these companies come
- 14 up to you and say, "How much money that we've given
- 15 to CTR has specifically been spent on
- 16 smoking-and-health-related research?"
- 17 A. They haven't asked that question because they
- 18 know that all of the money has been devoted to that
- 19 issue.
- 20 Q. They've never asked you that; have they, sir?
- 21 A. No, sir.
- 22 Q. Not any scientist from any of those companies
- 23 has ever asked you; have they?
- 24 A. No, sir, because they are well aware that we are
- 25 directing our attention to the fundamental disease STIREWALT & ASSOCIATES
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- 1 processes associated with smoking.
- 2 Q. And what you said on Friday with regard to these
- 3 $\,$ grants was that they're generally in the area of 80 $\,$
- $4\,$ to 85 thousand dollars, and they allow young people
- 5 just getting started to get their feet wet. Isn't
- 6 that what you said?
- 7 A. That's correct.
- 8 Q. And the vast majority of these grants of CTR
- 9 have been to young people just getting their feet
- 10 wet; --
- 11 A. No.
- 12 Q. -- correct?
- 13 A. I didn't say that. I said these grants -- these
- 14 grants have allowed young people to get a start, but
- 15 we've also funded well-established investigators,
- 16 such as the Nobel Prize winners that I've told you
- 17 about.
- 18 Q. Well let me direct your attention to page 4775,
- 19 when you were talking about the pages of the grants
- 20 on an exhibit that was shown to you by counsel, and
- 21 you said as follows: "And the amount of the award is
- 22 listed there, and I would tell you that our average
- 23 award is something like 80 or 85 thousand dollars a
- 24 year."
- 25 A. That's correct.

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1 Q. "So they're not huge grants. But they are very

```
good grants, especially for young people who are just
 2
    getting their -- their feet wet." Is that what you
 3
    said?
 4
 5
    A. Yes, sir.
              MR. WEBER: Objection, Your Honor, it's an
 6
7
     improper use of a deposition. It's not inconsistent.
              THE COURT: Sustained.
8
9
    BY MR. CIRESI:
    Q. Now, how many of the CTR awards were for people
10
11
    just getting their feet wet? How many?
    A. I can't tell you a specific number, but a
12
    substantial number. The point I was making is that a
    grant of this magnitude is of extreme value to
14
15
    someone who is just getting started in the biomedical
16
    research field.
17
    Q. And sir, have you done a survey to determine how
18
   many of these awards were to people just getting
19
    their feet wet?
20
   A. No. We've never done a tabulation.
21 Q. Have you, in the time you've been with the
22
    CTR --
23
         You've testified a number of occasions; correct?
2.4
    Α.
         No.
25
    Q. How many times have you testified in your life,
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    40 times?
 1
 2.
    A. Perhaps.
         Okay. Now in the entire time that you've been
 3
    with the CTR, have you gone out and asked the
 4
    grantees who are doing the work, "Do you believe this
    related to smoking and health?" Have you done that?
 6
7
    A. No, sir.
    Q.
        Have you directed anyone at the CTR to do that,
8
9
    sir?
10
   A. No, sir.
11 Q. Have the defendants asked the CTR to ever do
12
    that?
13 A. No.
14 Q. Now you talk --
         You talked about risks; did you not, sir? The
15
16
    risks for -- I think you talked about high
17
    cholesterol for heart disease and -- you remember
18
    that testimony?
19
    A. Yes.
20
    Q. And you were talking about various risk factors;
21
    is that right?
22
    Α.
         Yes.
    Q.
23
         I want to hand you the 1989 Surgeon General's
24
    report.
25
              MR. CIRESI: May I approach, Your Honor?
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                                                   4893
              THE COURT: All right.
 1
              (Document handed to the witness.)
 2
 3
         I'll hand you the entire report, sir, if you
    want to look anyplace to make sure it's in context,
    and also a part of it.
 6
              MR. WEBER: Do you have an exhibit number
```

- 7 on that, Mr. Ciresi?
- 8 MR. CIRESI: The 1989 is Exhibit 3821.
- 9 MR. WEBER: Thank you.
- 10 BY MR. CIRESI:
- 11 Q. Now on page 160, is there an estimated risk of
- 12 various activities?
- 13 A. Yes, there is.
- 14 Q. And do you know what that's for, sir?
- 15 A. This says "Table 13, Estimated Risk of Various
- 16 Activities," and then it lists activities or cause,
- 17 and then annual fatalities per one million exposed
- 18 persons.
- 19 Q. Is that for lung cancer?
- 20 A. No, this is in general. It's for a variety of
- 21 activities.
- 22 Q. Do you know what --
- 23 So it's for a variety of activities and which
- 24 activities cause death; correct?
- 25 A. Not necessarily cause. It says activity or STIREWALT & ASSOCIATES
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- 1 cause.
- 2 Q. Okay.
- 3 A. And then it lists the fatalities associated with
- 4 that risk.
- 5 Q. Now let's take a look, then, at that Table 13.
- 6 MR. WEBER: I'm going to object to any
- 7 questions about this, Your Honor. Dr. Glenn
- 8 testified about risk factors, not about risks of
- 9 comparable activities. This is beyond the scope of
- 10 what -- what his testimony was.
- 11 THE COURT: No, I think that's within the
- 12 scope.
- 13 BY MR. CIRESI:
- 14 Q. Now sir, on the left-hand margin it says
- 15 "Activity or cause;" correct?
- 16 A. Correct.
- 17 Q. And then it has "Annual fatalities for 1 million
- 18 exposed persons." Correct?
- 19 A. Yes.
- 20 Q. And for active smoking it was 7,000; correct?
- 21 A. That's correct.
- 22 Q. And for alcohol totally it was 541, 275 by
- 23 accident and 266 by disease; correct?
- 24 A. Yes.
- 25 Q. And then it went all the way down through work, STIREWALT & ASSOCIATES
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- 1 swimming, football, electrocution, et cetera;
- 2 correct?
 - A. Yes.
- 4 Q. Now when we talk about cause, doctor, last week
- 5 we talked about the Henle Koch postulates; didn't we?
- 6 Q. Yes.
- 7 Q. And today when you were talking about cause, you
- 8 were talking about universality. Do you remember
- 9 that word you used?
- 10 A. Yes.
- 11 Q. And by that you meant that every time someone

- 12 was exposed to something, universally a disease would
- 13 be produced, according to Henle Koch; correct?
- 14 A. No, I didn't say according to Henle Koch. I
- 15 talked about the universality of risk factors.
- 16 Q. You were talking about universality of risk
- 17 factors then?
- 18 A. Yes.
- 19 Q. Is that what you were saying?
- 20 A. Yes.
- 21 Q. Well the Henle Koch postulates were based on
- 22 19th century medical science; weren't they?
- 23 A. Yes.
- Q. And we went through those last week; didn't we,
- 25 sir?

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4896

- 1 A. Yes.
- Q. And we found that you yourself believed that
- 3 certain viruses would cause a disease regardless of
- 4 whether they met Henle Koch postulates; didn't you?
- 5 A. Yes.
- 6 Q. And one of those was Epstein-Barr; right?
- 7 A. Yes.
- 8 Q. Your judgment was that caused infectious
- 9 mononucleosis; correct?
- 10 A. It has been so stated, yes.
- 11 Q. And you agreed with that; didn't you?
- 12 A. Yes.
- 13 Q. It was a cause of infectious mononucleosis;
- 14 correct?
- 15 A. Yes.
- 16 Q. How many other causes of infectious
- 17 mononucleosis are there, sir?
- 18 A. I don't know.
- 19 Q. Many, aren't there?
- 20 A. Yes.
- 21 Q. All kinds of causes of infectious mononucleosis;
- 22 correct?
- 23 A. As I understand it, yes.
- 24 Q. Do you know how many cases of infectious
- 25 mononucleosis are caused by Epstein-Barr?

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- 1 A. No.
- 2 Q. Do you know how many are caused by the other
- 3 causes?
- 4 A. No.
- 5 Q. But you used the word "cause" in that effect;
- 6 don't you, sir?
- 7 A. I accept your use of the term "cause" in the lay
- 8 sense.
- 9 Q. And the medical scientists accept that; don't
- 10 they, sir?
- 11 A. In the lay sense, yes.
- 12 Q. Not in the lay sense. Werner Henle, who found
- 13 the Epstein-Barr virus as a cause of infectious
- 14 mononucleosis, used it in a medical sense; didn't he,
- 15 sir?
- 16 A. I don't know.

- 17 Q. You just don't know.
- 18 A. No.
- 19 Q. Okay. Do you know how many cases of lung cancer
- 20 are caused by smoking as contrasted with any other
- 21 cause?
- 22 A. I accept the word "cause" in the lay sense, and
- 23 I don't know the answer.
- 24 Q. You don't. But you do know that the attorney --
- 25 or excuse me, the Surgeon General since 1964 has used STIREWALT & ASSOCIATES
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- 1 the word "cause;" correct?
- 2 A. Yes.
- 3 Q. And explained the word "cause" in the Surgeon
- 4 General's report; correct?
- 5 A. Yes.
- 6 Q. And went and talked about the experimental
- 7 approach accepted by scientists which provides a
- 8 direct method for establishing whether an association
- 9 is causal; correct?
- 10 A. I don't follow your question.
- 11 Q. The Surgeon General in the 1964 report set forth
- 12 the experimental approach which provides a direct
- 13 method for establishing whether association is
- 14 causal; didn't he?
- 15 A. There is the argument and the discussion of
- 16 cause, causation, risk, and so forth, yes.
- 17 Q. He talks about the temporal association;
- 18 correct?
- 19 A. Yes.
- 20 Q. The consistency of the association.
- 21 A. I guess, yes.
- 22 Q. Do you know?
- 23 A. I don't know.
- Q. Have you read the Surgeon General's report?
- 25 A. The consistency, I don't -- I can't answer that.
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- 1 That's the part of your question I can't answer.
- 2 Q. So -- so you don't know whether that's a factor
- 3 or not; is that right?
- 4 A. Correct.
- 5 Q. Okay. Do you know if the strength of an
- 6 association is?
- 7 A. Roughly.
- 8 Q. Do you know?
- 9 A. Roughly.
- 10 Q. I didn't ask you roughly or vaguely. Do you
- 11 know?
- 12 A. Roughly.
- 13 Q. Just roughly. Well remember last week you said
- 14 that you don't guess, you either know or don't know?
- 15 Isn't that your sworn testimony?
- 16 A. Correct.
- 17 Q. Do you know or not know?
- 18 A. I roughly know that strength of association.
- 19 Q. Okay.
- 20 A. I'm not a statistician.
- 21 Q. Do you know if coherence is a factor used by

- 22 medical scientists to determine causation?
- 23 A. I think so.
- 24 Q. All right. Do you know if the specificity of an
- 25 association is used by medical scientists to STIREWALT & ASSOCIATES
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- 1 determine causation?
- 2 A. Yes.
- 3 Q. And sir, you are aware, are you not, that the
- 4 Surgeon General in 1964 and since that time has used
- 5 all of those factors to say from a scientific
- 6 standpoint there's a cause-and-effect relationship
- 7 between smoking and lung cancer?
- 8 A. Yes.
- 9 Q. And you know that eminent scientists from around
- 10 the world said the same thing; don't you?
- 11 A. Yes.
- 12 Q. Using that scientific methodology to determine
- 13 cause and effect; correct?
- 14 A. Yes.
- 15 Q. Now what was being argued about in Exhibit 11028
- 16 was what method you would use to determine causation,
- 17 direct or indirect; isn't that right?
- 18 A. I don't remember that document.
- 19 Q. Mr. Weber just showed it to you this morning.
- 20 Remember, he said it's the one I showed you last
- 21 week?
- 22 A. I didn't -- I didn't memorize the numbers of the
- 23 documents, Mr. Ciresi.
- 24 Q. That was the --
- That's fair enough, doctor. That's the one STIREWALT & ASSOCIATES
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4901

- 1 that -- where the three scientists came over from
- 2 England and met with members of the industry and met
- 3 with all of those scientific organizations. Do you
- 4 recall that one?
- 5 A. Yes.
- 6 Q. Okay. If you would direct your attention to
- 7 Exhibit 11028. It would be in volume two, sir.
- 8 A. It would be volume two, yes.
- 9 Q. Volume two.
- 10 A. And it is 11 --
- 11 Q. 028.
- 12 A. I have it.
- 13 Q. All right. And you'll recall that Mr. Weber
- 14 took you through a number of pages?
- 15 A. Yes.
- 16 Q. First of all, let's start with page 492.
- 17 A. All right.
- 18 Q. Now do you recall, sir, that last week we went
- 19 over this page?
- 20 A. Yes.
- 21 Q. And the next page; didn't we?
- 22 Q. Yes.
- 23 Q. And you'll recall that last week I went over
- 24 with you, first of all, that first paragraph.
- 25 A. Yes.

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4902

- 1 Q. It pointed out that "With one exception," and
- 2 that was the scientist from Yale, "the individuals
- 3 whom we met on that trip believed that smoking causes
- 4 lung cancer if by 'causation' we mean any chain of
- 5 events which leads finally to lung cancer and which
- 6 involves smoking as an indispensable link; "correct?
- 7 A. I remember seeing that, but I also remember
- 8 seeing further on in the document that they refute
- 9 their own statement --
- 10 Q. Well --
- 11 A. -- because other -- other -- other experts
- 12 equivocated.
- 13 Q. Excuse me, sir. Remember that we saw this
- 14 last -- last week?
- 15 A. I do.
- 16 O. Okay. And we also looked at the bottom of that
- 17 page; didn't we, sir?
- 18 A. Yes.
- 19 Q. Last week.
- 20 A. Yes.
- 21 Q. And we looked at this part about "The SAB of
- 22 TIRC and the group we met at the National Cancer
- 23 Institute, in Bethesda, broadly take the view that
- 24 causation is likely to be indirect; " correct?
- 25 A. Yes.

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4903

- 1 Q. So that of all the people that were met there,
- 2 and that's reported later in this document, there was
- 3 universality -- universality on the fact that smoking
- caused cancer, but some thought it was direct and
- 5 some thought it was indirect, --
- 6 A. That's not --
- 7 Q. -- with the exception of --
- 8 A. That's not corroborated by the document. If you
- 9 read further you'll see there's a great deal of
- 10 equivocation.
- 11 Q. Well let's go on. We're going to go through
- 12 that and see. "The SAB of TIRC and the group we met
- 13 at the National Cancer Institute, Bethesda, broadly
- take the view that causation is likely to be indirect." That's what it says; correct?
- 16 A. Correct.
- 17 Q. "Several hypothetical means by which this" --
- 18 and that's the indirect method; correct? That's
- 19 what's being referred to there.
- 20 A. I assume.
- 21 Q. Okay. "Several hypothetical means by which this
- 22 could occur were proposed but with no experimental
- 23 evidence to support any of them." Correct?
- 24 A. That's what it says.
- 25 Q. Over on the next page then. "Otherwise we found STIREWALT & ASSOCIATES
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- 1 general acceptance of the view that the most likely
- 2 means of causation is that tobacco smoke contains

- carcinogenic substances present in sufficient 3
- quantity to provide lung cancer when acting for a 4
- long time in a sensitive individual." Correct? 5
- A. That is the statement.
- Q. All right. So that some people felt it was 7
- 8 direct, some people felt it was indirect, based on
- these two pages; correct? 9
- 10 A. I don't know whether it's correct or not.
- That's what's written. 11
- Q. Okay. Now they said that also they felt there 12
- 13 was carcinogenic substances present in the tobacco
- smoke; correct?
- 15 A. I believe at that time many people believed
- 16 that.
- 17 Q. And it's known there's carcinogenic substances
- 18 in cigarette smoke; isn't it? Even today it's known
- 19 now; isn't it?
- 20 A. I'm sorry, I missed your --
- 21 Q. It is known today that there are carcinogenic
- 22 substances in tobacco smoke; correct?
- 23 A. It is -- it is known today that there are minute
- 24 quantities of carcinogens in tobacco smoke. Yes.
- Q. And -- and that was known by some of these STIREWALT & ASSOCIATES
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- defendants, as we saw, back in the early fifties;
- 2. correct?
- 3 A. That is what the documents state.
- And the Surgeon General has reported that in 4
- many of the Surgeon General reports; correct? 5
- 6 A. As I understand, yes.
- Q. And the Surgeon General reports have talked 7
- about the synergism between all of the carcinogens, 8
- not just one like benzopyrene; haven't they? 9
- 10
- A. Yes.Q. And the medical literature has talked about the 11
- 12 synergisms of all of the carcinogens in tobacco
- 13 smoke; --
- 14 A. Yes.
- 15 Q. -- hasn't it?
- And in this particular document there's 16
- 17 reference to the synergism of all of the carcinogens
- 18 in tobacco smoke; isn't there?
- A. I don't remember it in this document. 19
- 20 Q. You remember about the conclusion, I believe it
- 21 was number three -- may have been six, I can't recall
- 22 right now -- that talked about the fact that there
- was no super carcinogen? Do you remember that? 23
- A. Yes. 24
- 25 Q. It is number three. If you take a look at page STIREWALT & ASSOCIATES
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- nine, sir. 1
- A. All right.
- It says, "The direct carcinogenicity of smoke 3
- 4 condensate to animal tissue, which is consistent with
- 5 direct causation, is now fully confirmed but the
- evidence so far obtained makes it unlikely that this
- activity is due to any single 'super carcinogen' in

- 8 smoke." Correct?
- 9 A. That's what is written, yes.
- 10 Q. And you understand that to mean, sir, that there
- 11 are many carcinogens in tobacco smoke; don't you?
- 12 A. Yes.
- 13 Q. And they work in synergism; correct?
- 14 A. It does not say that, Mr. Ciresi. And this
- 15 statement made 40 years ago made the assumption that
- 16 a direct effect of tobacco smoke or tobacco smoke
- 17 condensates was the cause of lung cancer, and that's
- 18 since been shown to be an incomplete answer.
- 19 Q. Didn't say it was the only cause; does it? Does
- 20 it say that?
- 21 A. You are using "the cause of lung cancer."
- 22 Q. Did you ever hear me in any of my questions over
- 23 two and a half days ask you whether it was the only
- 24 thing that ever caused lung cancer? Did I ever say
- 25 that, sir?

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- 1 A. I don't --
- 2 MR. WEBER: Objection, Your Honor.
- 3 A. I don't know that.
 - MR. WEBER: That's argumentative.
- 5 THE COURT: No, you may answer that.
- 6 Q. I never said that; did I, sir?
- 7 A. I don't know, Mr. Ciresi.
- 8 Q. Well did you ever hear me say that?
- 9 A. I don't know that I heard you say that.
- 10 Q. Now --

4

- 11 And they're not saying here that it is the only
- 12 cause of lung cancer; are they? They're saying it's
- 13 a cause of lung cancer; are they not?
- 14 A. I don't know what they're saying, Mr. Ciresi.
- 15 They're talking about smoke condensates 40 years ago,
- 16 and they are trying to determine whether there are
- 17 carcinogens that are actually effective, I think.
- 18 Q. So you just don't know whether they're talking
- 19 about smoking as a cause of lung cancer or smoking as
- 20 the only cause in the entire world of lung cancer; is
- 21 that right?
- 22 A. I don't know.
- 23 Q. Now when Mr. Weber was taking you through this
- 24 exhibit, he took you up to page 497. And actually to
- 25 be fair, he started at 496. Can you turn to 496,

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- 1 please.
- 2 You remember he started at the bottom here, he
- 3 directed your attention down to "Others, including
- 4 the SAB" --
- 5 A. Yes.
- 6 Q. -- "and a group at the National Cancer
- 7 Institute, do not accept that a case has yet been
- 8 made that tobacco smoke is directly carcinogenic to
- 9 the human lung." Remember that?
- 10 A. Yes.
- 11 Q. And that goes back to the page we just saw where
- 12 they were talking about the TIRC and direct and

- 13 indirect; doesn't it?
- 14 A. I guess.
- 15 Q. "While accepting broadly that cigarette smoke
- 16 may be said to be capable of 'causing' lung cancer
- 17 they argue that the evidence favors some indirect
- 18 mechanism of causation." Do you see that?
- 19 A. That --
- It is written, yes.
- 21 Q. And by "they" who favor the indirect causation
- 22 approach, that's reference to the National Institutes
- of Health and the TIRC; correct?
- 24 A. I believe so.
- 25 Q. And then you read through that paragraph; STIREWALT & ASSOCIATES
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- 1 correct?
- A. Yes.
- 3 Q. And then you stopped at the end of that
- 4 paragraph; didn't you?
- 5 A. I think so, Mr. Ciresi.
- 6 Q. And at the very next paragraph, sir, it reads,
- 7 "The group at the National Cancer Institute despite
- 8 their lack of conviction of a direct causal
- 9 relationship nevertheless advised that the tobacco
- 10 industry must concern itself permanently with the
- 11 problem of the biological effect of smoking."
- 12 Correct?
- 13 A. Yes.
- 14 Q. They were saying they had to do direct smoking-
- 15 related research; correct?
- 16 A. No, it did not say that.
- 17 Q. They didn't say that. You don't think that
- 18 means that.
- 19 A. Didn't say that.
- 20 Q. "...the tobacco industry must concern itself
- 21 permanently with the problem of the biological
- 22 effects of smoking." What do you think the
- 23 biological effects of smoking are, sir? If you know.
- 24 A. I think that's a very broad question. If you
- $\,$ 25 $\,$ will ask me specifically, I'll try to answer.

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- 1 Q. Can you answer the question as it is posed? If
- 2 you can't, just tell me you can't.
- 3 A. No.
- 4 $\,$ Q. All right. So you do not understand what "the
- 5 biological effects of smoking" would be.
- 6 A. Yes, I do.
- 7 Q. Can cancer be a biological effect?
- 8 A. Many things could be a biological effect.
- 9 Q. I didn't ask you if many things could be. I
- 10 asked you if cancer could be a biological effect.
- 11 A. I think you could use that term.
- 12 Q. Can heart disease be a biological effect?
- 13 A. Yes.
- 14 Q. Can chronic obstructive pulmonary disease be a
- 15 biological effect?
- 16 A. Yes.
- 17 Q. Okay. Now in the paragraph up above that you

- 18 did read, it says that "Unfortunately so long as the
- 19 basic problems underlying the transformation of a
- 20 normal to a cancerous cell remain unsolved, theories
- 21 of direct causation must be largely -- largely
- 22 speculative and almost without exception incapable of
- 23 being tested experimentally." Correct?
- 24 A. No.
- 25 Q. Isn't that what it reads? Did I misread it? STIREWALT & ASSOCIATES
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- 1 A. Yes.
- 2 Q. "...and almost without exception incapable," I'm
- 3 sorry, "of being tested experimentally." Correct?
- 4 A. I accept your correction.
- 5 Q. Okay. And do you know if there were inhalation
- 6 tests done that confirmed in the industry's judgment
- 7 the direct causation?
- 8 MR. WEBER: Your Honor, let me object
- 9 because -- just so the record's clear, according to
- 10 the realtime transcript the reference in the document
- 11 $\,$ is to "indirect," and what Mr. Ciresi said was
- 12 "direct," and I -- just so it's clear.
- MR. CIRESI: I believe I corrected it.
- 14 THE COURT: He -- it's been corrected, I
- 15 believe.
- MR. WEBER: I thought you corrected a
- 17 different issue. But -- but with that, go ahead.
- 18 I'm sorry for the interruption.
- 19 Q. Well let me --
- Just so the record's perfectly clear, doctor,
- 21 I'll read it again. "Unfortunately so long as the
- 22 basic problems underlying the transformation of a
- 23 normal to a cancerous cell remain unsolved, theories
- 24 of indirect causation must be largely speculative and
- 25 almost without exception incapable of being tested STIREWALT & ASSOCIATES
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- 1 experimentally." Have I read that correctly?
- 2 A. You did.
- 3 Q. Okay. And the indirect causation was the theory
- 4 being espoused by the TIRC at that time; correct?
- 5 A. I don't think that it was a theory being
- 6 espoused by the TIRC. I think that this statement
- 7 is -- is prophetic in a way because it acknowledges
- 8 that cause and risk factors of lung cancer are --
- 9 were still unknown and they -- they still are not
- 10 clear today. But it -- this is an acknowledgment
- 11 that the sort of research that has to be undertaken
- 12 has to address both direct and indirect factors.
- 13 Q. Sir, --
- 14 A. And --
- 15 Q. -- the theory being espoused in this document as
- 16 reported by the TIRC was indirect causation; correct?
- 17 A. Mr. Ciresi, as a matter of common courtesy I
- 18 don't interrupt you.
- 19 Q. Well I'm not going to say anything in regard to
- 20 that, sir.
- 21 My question is very simple. All right? The
- 22 record will reflect whether I interrupted you or you

```
interrupted me. If I did, I apologize. Now please
24
    listen to my question and I will restate it.
25
         Is it reported that, in this document, that the
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                                                   4913
    TIRC was advocating a theory of indirect causation?
    "Yes" or "no."
 2
    A. Yes.
 3
 4
    Q. Thank you.
        Now do you know if the industry was aware of
 5
    tests which they believed confirmed -- animal tests
 6
7
    that confirmed causation?
    A. No, I'm not aware of that, because no animal
 8
9
    experiments, inhalation experiments had ever
10 demonstrated this.
11 Q. Never have; correct?
12 A. To my knowledge, never.
13
   Q. All right. Can you direct your attention,
    sir --
14
              THE COURT: Mr. Ciresi, I wonder if we
15
16
    should recess for lunch.
17
              MR. CIRESI: If it's an appropriate time,
18
    Your Honor.
19
             THE COURT: Okay. We'll recess for lunch
20 and reconvene at 10 minutes to 2:00.
             THE CLERK: Court stands in recess.
21
22
              (Recess taken.)
23
24
25
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                                                   4914
 1
                        AFTERNOON SESSION.
              THE CLERK: All rise. Court is again in
 2
 3
    session.
 4
              (Jury enters the courtroom.)
 5
              THE CLERK: Please be seated.
              THE COURT: Counsel.
 6
              MR. CIRESI: Thank you, Your Honor.
7
         Good afternoon, ladies and gentlemen.
8
              (Collective "Good afternoon.")
9
10 BY MR. CIRESI:
11 Q. Good afternoon, doctor.
12 A. Good afternoon, sir.
13 Q. Now doctor, when we broke you said you were -- I
14
    think you said never, to your knowledge, had animal
15
    experiments, inhalation experiments, ever
16
    demonstrated that smoking caused lung cancer;
17
    correct?
18
    A. Correct.
    Q. Can you direct your attention, please, to
20
    Exhibit 21905, which would be in volume two.
    A. Yes, sir, I see that.
21
        All right. This is a document that's already in
22
    evidence.
23
24
        Have you seen this document before, doctor?
25 A. I'm not sure, Mr. Ciresi. I may have in times
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- 1 past.
- 2 Q. This is a document of Gallaher Limited which was
- 3 a company of American Tobacco, it's dated April 3rd,
- 4 1970, and the subject is the "Auerbach/Hammond Beagle
- 5 Experiment." Do you see that?
- 6 A. Yes.
- 7 MR. BERNICK: Your Honor, object. He said
- 8 Gallaher was part of American Tobacco. That's just
- 9 not so. It's an affiliate of American Tobacco. It
- 10 was owned by American Brands.
- MR. CIRESI: And American Brands owned
- 12 American Tobacco and Gallaher.
- 13 Q. Now when you looked at this document before, did
- 14 you ascertain whether it had been provided to
- 15 American?
- 16 A. I'm not sure I saw this, Mr. Ciresi, but I'd be
- 17 happy to try to respond.
- 18 Q. Okay. Now do you know if the Auerbach work was
- 19 funded by CTR?
- 20 A. No, I don't believe it was.
- 21 Q. Do you know if CTR funded work at Battelle?
- 22 A. Yes.
- 23 Q. And do you know if Battelle conducted animal
- 24 inhalation tests?
- 25 A. I believe so, yes.

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- 1 Q. And do you know if they confirmed what Dr.
- 2 Auerbach found?
- 3 A. If they confirmed what Dr. Auerbach --
- 4 Q. Found.
- 5 A. -- found. You'd have to tell me what he found.
- 6 Q. Well do you know anything about the Auerbach
- 7 studies on beagles?
- 8 A. I know something about it.
- 9 Q. Do you know if the same type of tests were
- 10 conducted by Battelle, funded by CTR, which found the
- 11 same things that Dr. Auerbach found? "Yes" or "no"
- 12 or you don't know.
- 13 A. I don't know.
- 14 Q. Okay. Now can you direct your attention, sir,
- 15 to page two of this exhibit. You do see the subject
- 16 is the Auerbach-Hammond beagle experiment; correct?
- 17 A. Yes.
- 18 Q. All right. And on page two, number three, it is
- 19 stated there by the general manager of research for
- 20 Gallaher in a memo that was directed to the general
- 21 manager -- or excuse me, the managing director as
- 22 follows: "However, in spite of the qualifications in
- 23 one and two, we believe that the Auerbach work
- 24 proves -- proves beyond reasonable doubt that fresh
- 25 whole cigarette smoke is carcinogenic to dog lungs STIREWALT & ASSOCIATES
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- and therefore it is highly likely that it is
- 2 carcinogenic to human lungs." Do you see that?
- 3 A. I see that.

- 4 Q. He goes on to state, "It is obviously impossible
- 5 to be certain of the extrapolation from an animal
- 6 lung to a human lung, but we have to bear in mind
- 7 that the anatomy of a dog is relatively close to
- 8 human anatomy and the type of tumor found in the dog
- 9 was the same type as found in heavy smokers." Do you
- 10 see that?
- 11 A. I see that.
- 12 Q. Were you aware of this?
- 13 A. I -- I'm aware of -- of Dr. Auerbach's
- 14 interpretation, but it was subsequently refuted.
- 15 Q. Sir, were you aware of this finding by Dr.
- 16 Auerbach?
- 17 A. I'm not sure this was a finding, because the --
- 18 it subsequently did not hold up to scrutiny.
- 19 Q. Are you aware that Gallahers felt it was beyond
- 20 a reasonable doubt that it proved --
- 21 A. I see that statement by the scientist at -- at
- 22 Gallaher.
- 23 Q. Can you go on, then, to the last page of this
- 24 document.
- 25 A. Yes, sir.

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4918

- 1 Q. And do you see in the last paragraph, Mr. Tughan
- 2 states as follows, "Apart from Auerbach's work,
- 3 Dontenwill's work and the preliminary results from
- 4 Harrogate all point to the fact that under suitable
- 5 conditions fresh whole smoke inhalation in animals
- 6 will produce pre-cancerous changes and, in certain
- 7 instances, true cancers which are similar to those
- 8 found in human smokers." Do you see that?
- 9 A. I see that statement, yes.
- 10 Q. Are you aware of the -- of Dontenwill's work?
- 11 A. No, I'm not familiar with that.
- 12 Q. Are you --
- 13 Are you familiar with the work done at
- 14 Harrogate?
- 15 A. No.
- 16 Q. You know that Harrogate was a research
- 17 laboratory in England set up by the tobacco industry?
- 18 A. Yes.
- 19 Q. Has anybody ever provided you with that
- 20 information?
- 21 A. No.
- 22 Q. Mr. Tughan goes on to state then, "It therefore
- 23 seems to us it is more than coincidence that
- 24 experimental evidence is building up in this
- 25 direction from several independent research

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- 1 organizations, each of which is of very high
- 2 caliber." Do you see that?
- 3 A. I see that.
- 4 Q. And you're not aware of any of that work; are
- 5 you, sir?
- 6 A. I'm not aware of --
- 7 Q. Any of that work.
- 8 A. I'm not aware of any of the work from Dontenwill

- 9 or Harrogate, no.
- 10 Q. Okay. Can you turn back one page, then, and
- 11 look at number five.
- 12 A. Yes, sir.
- 13 Q. "Although the results of the research would
- 14 appear to us to remove the controversy regarding the
- 15 causation of the majority of human lung cancer,
- 16 it" --
- 17 A. Excuse me, sir, number five says
- 18 "Unfortunately" --
- 19 Q. I'm sorry, six.
- 20 A. -- "the research" --
- 21 Q. I'm sorry, sir, number six.
- 22 "Although the results of the research would
- 23 appear to us to remove the controversy regarding the
- 24 causation of the majority of human lung cancer, it
- does not help us directly with the problem of how to STIREWALT & ASSOCIATES
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- 1 modify our cigarettes." Do you see that?
- 2 A. I do.
- 3 Q. And the problem of how to modify the cigarettes
- 4 is that there were a number of carcinogens in
- 5 cigarettes; isn't that correct?
- 6 A. It doesn't say that. It just says "it doesn't
- 7 help us directly with the problem of how to modify
- 8 our cigarettes."
- 9 Q. Sir, have you come to learn over the period of
- 10 time that you've been with the CTR, or indeed before
- 11 that, that there were a number of carcinogens in
- 12 cigarette smoke?
- 13 A. Yes.
- 14 Q. And did anybody ever tell you that the cigarette
- 15 companies could remove one and not the other?
- 16 A. No.
- 17 Q. Did they ever tell you they could remove all of
- 18 them?
- 19 A. No.
- 20 Q. Do you know of any attempt they made to remove
- 21 all of them?
- 22 A. No.
- 23 Q. Have you ever seen any studies they conducted
- 24 trying to remove all of the carcinogens?
- 25 A. No.

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- 1 Q. In your discussions with Dr. Spears did you ever
- 2 ask him, "Have you ever tried to remove the
- 3 carcinogens?"
- 4 A. No.
- 5 Q. Have you ever had that discussion with anyone --
- 6 A. No.
- 7 Q. -- at any of the companies?
- 8 A. No
- 9 Q. Did you ever have that discussion with any
- 10 member of the SAB board?
- 11 A. No.
- 12 Q. Can you direct your attention, then, sir, to
- 13 Exhibit 10312, which would be in volume one. This is

- a Philip Morris document dated February 5th, 1970
- 15 from Mr. Saleeby, who was a scientist at Philip
- Morris, to the senior vice-president and a member of 16
- 17 the board of directors, Mr. Landay. Have you seen
- this before?
- 19 I'm sorry, sir, I can't find it. It's 10212?
- I'm sorry, 10312. And I apologize, I thought 20 Ο.
- 21 you had it, sir.
- 22 A. Thank you.
- 23 Q. Do you have it now?
- 24 A. Yes.
- 25 Q. Okay. And do you see that it's directed to Mr. STIREWALT & ASSOCIATES
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- Landay? 1
- A. Yes, I can read that. 2.
- Q. And it's from Mr. Saleeby? 3
- 4 A. Saleeby.
- Saleeby. Did you know Mr. Saleeby? 5 Q.
- No. 6 Α.
- Q. And in the first paragraph, do you see the 7
- 8 sentence that starts, about halfway through it, "The
- 9 important finding is that two of the 86 dogs which
- 10 started the test developed 'early squamous cell
- 11 bronchial carcinoma'" --
- Do you see that? 12
- A. I do. 13
- 14 Q. -- "i.e., the most common lung cancer occurring
- 15 in man." Correct?
- 16 A. Yes.
- 17 Q. And do you know if that was the most common lung
- 18 cancer occurring in man at that time?
- 19 A. Yes.
- Is it today? 20 Q.
- 21
- A. Yes, it still is.
 Q. And do you see where it's then reported, "This 22
- 23 is the first time that cigarette smoke as a direct
- 24 agent has produced lung cancer in any animal in any
- 25 reliably conducted experiment?"

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- A. I see that. 1
- So we see that Philip Morris felt that Q.
- Auerbach-Hammond was reliable; correct?
- A. Well I would say that Mr. Saleeby felt that. 4
- 5 Q. And he was reporting to the senior
- vice-president and member of the board of directors
- 7 of the company; correct, sir?
- A. I will accept that. I didn't know Mr. Landay. 8
- 9 Q. And can you direct your attention to Exhibit
- 10 12296, which is back in volume two, sir.
- 11 A. I have that.
- This is a memo on RJR header -- letterhead. Do 12 Q.
- 13 you see that?
- 14 A. I see that.
- 15 Q. Dated December 22nd, 1971?
- 16 A. Yes.
- 17 Q. Subject: "Meeting at Council for Tobacco
- 18 Research, December 21, 1971; correct?

- 19 A. Correct.
 20 MR. CIRESI: Your Honor, we'd offer Exhibit
 21 12296.
 22 MR. WEBER: No objection, Your Honor.
 23 THE COURT: Court will receive 12296.
 24 THE REPORTER: I don't think we have it.
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- 1 THE REPORTER: I don't think we have it.
- 2 BY MR. CIRESI:
- 3 Q. Now this is a report of a meeting that was held
- 4 at the CTR to discuss the Auerbach -- Auerbach

THE COURT: What?

- 5 smoking experiments on dogs; correct?
- 6 A. Yes.

25

- 7 Q. Have you seen this before, sir?
- 8 A. Yes.
- 9 Q. When did you first see it?
- 10 A. Probably a year ago.
- 11 Q. Who provided it to you?
- 12 A. I -- I can't recall. It was in connection with
- 13 a previous deposition.
- 14 Q. Okay. Now you see that present at the meeting
- 15 were three individuals from The Council for Tobacco
- 16 Research?
- 17 A. Yes.
- 18 Q. Mr. Lisanti?
- 19 A. Dr. Lisanti.
- 20 Q. He's a doctor; is that right?
- 21 A. Yes.
- 22 Q. Associate research director?
- 23 A. Yes.
- 24 Q. Okay. Mr. Hoyt, who was the executive director
- of The Council for Tobacco Research?

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- 1 A. I don't know what his title was in 1971, but he
- 2 was the executive officer.
- 3 Q. And Robert C. Hockett, who was the associate
- 4 scientific director?
- 5 A. Dr. Hockett was the associate scientific
- 6 director.
- 7 Q. And there's three individuals present from
- 8 Philip Morris; correct?
- 9 A. Yes.
- 10 Q. Mr. Holtzman?
- 11 A. Yes.
- 12 Q. Mr. Saleeby. Same Mr. Saleeby; correct?
- 13 A. Yes.
- 14 Q. And Dr. Helmut Wakeham, who was the
- vice-president of research and development; correct?
- 16 A. Yes.
- 17 Q. Mr. Holtzman was an in-house lawyer; wasn't he?
- 18 A. I -- I believe Mr. Holtzman was an attorney.
- 19 Q. And from RJR was an in-house lawyer, Mr. Roemer,
- 20 and Dr. Murray Senkus, who was head of research and
- 21 development; correct?
- 22 A. I will accept that. I don't know that.
- 23 Q. Do you know if Mr. Roemer was an in-house

- 24 lawyer?
- 25 A. I don't know that, no, sir.

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- 1 Q. Okay. Now do you see here that there was -- in
- 2 the "Background," that the National Cancer Institute
- 3 under the direction of Gio Gori was negotiating with
- 4 Dr. Auerbach to conduct further smoking experiments
- 5 on dogs?
- 6 A. I see that.
- 7 Q. And the objective in that experiment was to
- 8 determine the effect of nicotine on smoking dogs;
- 9 correct?
- 10 A. That is what is stated.
- 11 Q. And the Scientific Advisory Board had met on
- 12 December 10th to 12th of 1971 regarding that;
- 13 correct?
- 14 A. It so states, yes.
- 15 Q. And they were looking at this proposed study on
- 16 nicotine and they felt it would be meaningless from a
- 17 medical standpoint; is that right?
- 18 A. Yes.
- 19 Q. And that we should make every effort to convince
- 20 NCI to abandon the experiment; correct?
- 21 A. Right.
- 22 Q. And "we" was the CTR and the companies; correct?
- 23 A. I guess so, yes.
- Q. Okay. And then he sets forth in this report,
- 25 Mr. Vassallo, who was a vice-president of research STIREWALT & ASSOCIATES
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- 1 and development for RJR -- I'm sorry, I misspoke,
 2 sir.
- 3 Dr. Senkus sets forth in this report the basis
- 4 for the attempt to convince the NCI not to conduct
- 5 this experiment on nicotine; correct?
- 6 A. Yes.
- 7 Q. And the reasoning went as follows: "Smoke will
- 8 be delivered to the -- to the dogs through an
- 9 incision in the throat, thus whole smoke will be
- 10 presented to the lungs. During human smoking, smoke
- 11 is first presented to the mouth where the aldehydes
- 12 are removed from the smoke." Do you see that?
- 13 A. I do.
- 14 Q. What's an aldehyde?
- 15 A. A chemical compound that can be very irritating.
- 16 Q. What kind of chemical compound?
- 17 A. Well aldehydes -- formaldehyde is an aldehyde.
- 18 Q. Do you know its biological -- its chemistry, its
- 19 chemical composition, sir?
- 20 A. No, I can't give you the chemical formula. But
- 21 formaldehyde is the aldehyde of formic acid. It is a
- 22 degratory product.
- 23 Q. But you do not know the chemical composition;
- 24 correct?
- 25 A. No, sir.

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- 1 Q. And sir, are you aware of any study conducted by
- 2 CTR or these companies, Philip Morris or RJR, which
- 3 would suggest, imply, or lead one to the conclusion
- 4 that aldehydes are selectively selected out in the
- 5 mouth during smoking?
- 6 A. I can't cite any studies. It so states here,
- 7 but I don't have any personal knowledge of this, no.
- 8 Q. You've never heard of any such thing; have you?
- 9 Any such study?
- 10 A. Well I don't know whether I have or not. It
- 11 seems vaguely familiar, but I -- I don't know that I
- 12 know that.
- 13 Q. What seems vaguely familiar?
- 14 A. That aldehydes are detoxified. But I don't know
- 15 that. I simply don't know.
- 16 Q. Okay. So this again is not something you would
- 17 quess at. You either know or don't know; correct,
- 18 sir?
- 19 A. Yes.
- 20 Q. Okay. At least you can't help us by pointing to
- 21 any study that would ever suggest, imply, or direct
- 22 one to the conclusion that aldehydes are selectively
- 23 removed in the mouth; correct?
- MR. WEBER: Objection, Your Honor, that's
- 25 been asked and answered, that very question.

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- 1 THE COURT: It's been asked and answered.
- 2 BY MR. CIRESI:
- 3 Q. Now sir, if aldehydes are not selectively
- 4 removed in the mouth, then the smoke wouldn't be any
- 5 different inhaled through the mouth as inserted
- 6 through an incision in the throat; isn't that
- 7 correct?
- 8 A. I don't --
- 9 I can't say that, no. I don't know that.
- 10 Q. You don't know. By that you mean you don't know
- 11 one way or the other; correct, sir?
- 12 A. I don't know one way or the other.
- 13 Q. Now do you know if the CTR and Reynolds and
- 14 Philip Morris went to the NCI and attempted to
- 15 convince them not to conduct this study on nicotine?
- 16 A. I don't know.
- 17 Q. Do you know if Dr. Gori agreed to meet with
- 18 them?
- 19 A. It says so in the memorandum.
- 20 Q. The next page; doesn't it?
- 21 A. Yes.
- 22 Q. And Dr. Gori was with the NCI; isn't that right?
- 23 A. Yes.
- 24 Q. And do you know if Dr. Gori was a consultant to
- 25 the tobacco industry?

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- 1 A. No, I don't know that.
- 2 Q. Do you know if they ever paid him any money?
- 3 A. I don't know.
- 4 Q. Do you know if he ever asked them to suggest

- 5 that he head up a Tobacco Working Group?
- 6 A. I don't know.
- 7 Q. Do you know if they asked him to lobby -- if he
- 8 asked them to lobby the White House on his behalf?
- 9 MR. WEBER: Objection, Your Honor, this is
- 10 argumentative and there's no foundation for it.
- 11 THE COURT: Well he can answer it if he
- 12 knows.
- 13 Q. Do you know?
- 14 A. I don't know.
- 15 Q. Do you know how many studies, sir, confirmed the
- 16 Auerbach studies, at Harrogate, Dontenwill or
- 17 anyplace else?
- 18 A. My information is that none of them confirmed
- 19 Dr. Auerbach's conclusions.
- 20 Q. Do you know how many at Harrogate or from
- 21 Dontenwill or anyplace else confirmed it?
- 22 A. No.
- 23 Q. Do you know?
- 24 No?
- 25 A. No.

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- 1 Q. Can you direct your attention, then, back to
- 2 Exhibit 11027, which would be the last exhibit in
- 3 volume one. And you were directed there by Mr.
- 4 Weber. Do you recall that document?
- 5 A. Yes.
- 6 Q. Marked "CONFIDENTIAL." It was one of the
- 7 Tobacco Standing Committee, which was a research arm
- 8 of The Tobacco Research Council in England?
- 9 A. Yes.
- 10 Q. Okay. And it dealt with discussions with
- 11 various research directors of the cigarette
- 12 companies. Do you remember that?
- 13 A. It is a report on research into smoking and
- 14 health.
- 15 Q. And it relates to a trip to the United States in
- 16 September and October of 1964; correct?
- 17 A. It so states.
- 18 Q. And Mr. Weber asked you to read from a number of
- 19 the pages here. Do you recall that?
- 20 A. Yes.
- 21 Q. He had directed your attention, I believe, to
- 22 page 290 and asked you to start there under "A.M.A
- 23 Research into Smoking and Health, " and you read on
- 24 for a few pages. Do you remember that?
- 25 A. Yes.

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- 1 Q. Do you know whatever happened to that AMA
- 2 research?
- 3 A. Well ultimately the agreement between the
- 4 American Medical Association and the tobacco
- 5 companies came to an end. I don't know why.
- 6 Q. Do you know if the tobacco industry pulled the
- 7 funding from the AMA?
- 8 A. I don't know.
- 9 Q. Can you direct your attention, then, to page --

- 10 you --
- 11 You read through page 290 and 291, and then you
- 12 went over to 292. Do you remember that, sir?
- 13 A. Yes.
- 14 Q. Okay. Can you go to 292 where you stopped. You
- 15 remember Mr. Weber asked you to read paragraph two.
- 16 If we could move it down just a little bit, Ms.
- 17 Sutton. Thank you.
- You read paragraph two, main reason why people
- 19 smoke is the nicotine. Do you see that?
- 20 A. Yes.
- 21 Q. Now Dr. Seevers, he was doing research on
- 22 nicotine; wasn't he?
- 23 A. I believe so.
- Q. He wasn't researching into lung cancer; was he?
- 25 A. No.

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- 1 Q. No. And he found nicotine addictive; didn't he?
- 2 A. I think that that was his conclusion, yes.
- 3 Q. And that's set forth in all the paragraphs that
- 4 you didn't read there, paragraph three, paragraph
- 5 four, paragraph five, paragraphs six and seven. You
- 6 go over to the next page, the addictive experiments
- 7 with monkeys that were being conducted. Did you read
- 8 all those paragraphs?
- 9 A. No, sir.
- 10 Q. Did anybody direct you to those to read?
- 11 A. No, sir.
- 12 Q. Okay. And then you went on to the last page and
- 13 you read Dr. Seevers' comments about the Surgeon
- 14 General's Advisory Committee; correct?
- 15 A. Yes.
- 16 Q. And I believe you said that -- or Mr. Weber said
- 17 that Dr. Seevers said it was a committee of prima
- 18 donnas; is that right?
- 19 A. That was what was written, yes.
- 20 Q. Have you ever known a doctor to be a prima
- 21 donna?
- 22 A. Yes, sir.
- 23 Q. Have you?
- 24 A. Yes, sir.
- 25 Q. Now did you consider all of the members of the STIREWALT & ASSOCIATES
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- 1 Surgeon General's committee in 1964 prima donnas, all
- 2 those eminent physicians that were on there?
- 3 A. Well I only knew one of them on the -- on that
- 4 committee at that time.
- 5 Q. Who did you know?
- 6 A. Dr. John Hickham, who was one of my teachers.
- 7 Q. Did you think he was a prima donna?
- 8 A. No, sir.
- 9 Q. No. Did you think all the doctors on the 1967
- 10 and 1968 and 1969 and 1971 or 1972 or 1973 or '74 or
- 11 '75 or '76, or any of the Surgeon General's reports
- 12 all the way up through 1994, did you think they were
- 13 all prima donnas?
- MR. WEBER: Objection, Your Honor, it's

- 15 argumentative.
- 16 THE COURT: No, you may answer.
- 17 A. That was Dr. Seevers' opinion, and Dr. Seevers
- 18 like everybody else is entitled to his opinion.
- 19 Q. I understand that. I'm asking you your opinion,
- 20 sir. Did you think they were all prima donnas in all
- 21 of those Surgeon General's reports during the
- 22 sixties, the seventies, the eighties, and into the
- 23 nineties? Did you?
- 24 A. I had no reason to make any judgment about that.
- 25 Q. You had no reason to call any of them prima STIREWALT & ASSOCIATES
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- 1 donnas; did you, sir?
- 2 A. No.
- 3 Q. And in fact Surgeon General report after Surgeon
- 4 General report after Surgeon General report found
- 5 that smoking causes diseases; didn't they?
- 6 A. If we come back to the definition of the word
- 7 "cause."
- 8 Q. Yes. The scientific definition of cause that we
- 9 discussed earlier today, you and I. They found it
- 10 time and time and time again; didn't they, sir?
- 11 A. No, sir. We still have the -- the dichotomy
- 12 between "cause" in the broad, general sense and
- 13 "cause" in the specific sense.
- 14 Q. I'm talking cause, sir, as found by these
- 15 scientists by using scientific methodology of looking
- 16 at experiments, looking at associations, looking at
- 17 coherency, looking at strength of association, all of
- 18 those scientific methodologies, they found it time
- 19 after time; didn't they?
- 20 A. No, sir. We still have the -- the difference of
- 21 definition of "cause." And I accept the Surgeon
- 22 General's use of the term "cause" and I think it's
- 23 appropriate because he was attempting to educate
- 24 people about risk factors.
- 25 Q. Sir, he used the word "cause" based on STIREWALT & ASSOCIATES
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- 1 scientific methodology that you and I discussed this
- 2 morning. Do we have to go through that again?
- 3 MR. WEBER: Object to the commentary, Your
- 4 Honor
- 5 Q. Do you want to go through that again?
- 6 A. No, sir, I don't want to, but I'd be glad to if 7 you want.
- 8 Q. All right. Well then let's do it again.
- 9 The temporal association, the consistency of the
- 10 association, the strength of the association, the
- 11 coherence, the specificity, all of those factors, the
- 12 epidemiology, the toxicology test, all of those that
- 13 are taken together by scientists to determine whether
- 14 there's cause and effect, that's what was done in the
- 15 Surgeon General's report; correct?
- MR. WEBER: Objection, Your Honor, it's
- 17 asked and answered and argumentative.
- 18 THE COURT: It's not argumentative. You
- 19 can answer it.

- 20 Q. Isn't that correct, sir?
- 21 A. Yes, sir, all of that's correct. But --
- 22 Q. And that --
- 23 A. -- you still have not settled the issue of
- 24 "cause." And I'd be happy to explain that again if
- 25 you want me to.

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- 1 Q. No, because you don't want to accept "cause"
- 2 because you want it to be according to the Henle Koch
- 3 postulates; isn't that right?
- 4 A. No, sir, not exactly. What I want to do is to
- 5 be scientifically accurate. And we know that 93
- 6 percent of smokers never get any lung disease. We
- 7 also know that smokers are more prone to have lung
- 8 cancer than are non-smokers. So, you know, the
- 9 evidence is -- is out there, but it's not conclusive.
- 10 Q. Doctor, you want "cause" based on Henle Koch
- 11 postulates. That's what you want. You want
- 12 universality; correct?
- MR. WEBER: Objection, Your Honor, it's
- 14 just asked and answered.
- THE COURT: Well that was a different
- 16 question, universality.
- 17 Q. Isn't that right, sir?
- 18 A. No, sir.
- 19 Q. You accept cause of infectious mononucleosis
- 20 even though you know there's all kinds of other
- 21 causes for it; isn't that right? Or Epstein-Barr.
- 22 You accept that; don't you?
- 23 A. Well I don't want to argue with you, but I think
- 24 we've answered this question before, and I -- my only
- 25 comment is that we've got to accept the term "cause" STIREWALT & ASSOCIATES
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- 1 in the broadest sense.
- 2 Q. Sir, with regard to infectious mononucleosis,
- 3 you accept that the Epstein-Barr causes it; don't
- 4 you?
- 5 A. Among other things.
- 6 MR. WEBER: Objection, Your Honor, asked
- 7 and answered.
- 8 THE COURT: It's been asked and answered.
- 9 Q. You don't differentiate "cause" with regard to
- 10 infectious mononucleosis; do you?
- 11 A. There are many causes.
- 12 Q. Do you -- do you differentiate --
- 13 Is that scientific cause, Epstein-Barr?
- 14 A. I don't understand the question.
- 15 Q. Question is very simple: From a scientific
- 16 standpoint, does Epstein-Barr cause infectious
- 17 mononucleosis?
- MR. WEBER: Objection, Your Honor, asked
- 19 and answered.
- THE COURT: No, this is a new question.
- 21 A. It might.
- 22 Q. It might?
- 23 A. It might in a given individual.
- 24 Q. Didn't you say this morning and last week that

- 25 it did cause infectious mononucleosis?

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- 1 A. It can.
- 2 Q. And other things can cause it, too; correct?
- 3 A. Yes.
- 4 Q. And cigarette smoking can cause lung cancer in
- 5 individuals; can't it?
- 6 A. Again we come back to the definition of "cause."
- 7 Q. Same thing as Epstein-Barr and infectious
- 8 mononucleosis?
- 9 A. No, sir, I don't think so. They're apples and
- 10 oranges and there's no -- there's no way to compare
- 11 the two.
- 12 Q. Do you know what -- let me strike that.
- You said earlier you don't even know how many
- 14 other causes for infectious mononucleosis there is.
- 15 A. I don't think anybody does.
- 16 Q. But didn't you say that?
- 17 A. Yes.
- 18 Q. But yet you still say that Epstein-Barr causes
- 19 infectious mononucleosis; correct?
- 20 A. Yes.
- 21 Q. Okay. Now let's deal with lung cancer. In the
- 22 same fashion, wouldn't you agree that cigarette
- 23 smoking causes lung cancer?
- 24 A. I accept the Surgeon General's definition.
- 25 Q. Thank you.

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- 1 Now can you direct your attention back to 11028
- then, which would be the first exhibit in book one.
- 3 I'm sorry, in book two.
- 4 A. I have that.
- 5 Q. Now you recall before we broke this morning we
- 6 were talking about direct and indirect --
- 7 A. Yes.
- 8 Q. -- cause as articulated in this memo between the
- 9 people who had been interviewed by these individuals
- 10 who came over from England. Do you remember that?
- 11 A. Yes.
- 12 Q. Okay. And sir, can you direct your attention,
- 13 then, to the page eight of that memorandum.
- 14 A. Yes.
- 15 Q. Now do you remember I asked you whether or not
- 16 it wasn't true that in this memorandum it was being
- 17 reported that TIRC said there was indirect causation,
- 18 but they agreed there was causation? Do you recall
- 19 that?
- 20 A. I recall the questions, yes.
- 21 Q. Okay. Now can you direct your attention to the
- 22 bottom where they state their conclusions. Number
- 23 one, "Although there remains some doubt as to the
- 24 proportion of the total lung cancer mortality which
- 25 can fairly be attributed to smoking, scientific

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- 1 opinion in the U.S.A. does not now seriously doubt
- 2 that the -- that the statistical correlation is real
- 3 and reflects a cause and effect relationship." Do
- 4 you see that?
- 5 A. I see that statement.
- 6 Q. And that's six years before the Surgeon General
- 7 report; correct?
- 8 A. Yes.
- 9 Q. And then they go -- they go on with the second
- 10 conclusion, "There remains an area for debate as to
- 11 what is meant by 'causation.' Opinion differs as to
- 12 whether or not the cigarette smoke is likely to exert
- 13 its effect by direct action on the lung. An indirect
- 14 mechanism of causation is thought by some to be more
- 15 likely." Do you see that?
- 16 A. Yes.
- 17 Q. Now sir, isn't it true that it was the TIRC, the
- 18 forerunner of the CTR, that thought it was the
- 19 indirect method of causation that was more likely
- 20 than the direct method, as reported in this
- 21 memorandum?
- 22 A. Well this memorandum was written by people that
- 23 I didn't know, and I don't know what their
- 24 qualifications are nor do I know whether they are
- 25 accurately reflecting conversations that they had.

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- 1 So there are many if's here.
- 2 I think to get a sense of what the Scientific
- 3 Advisory Board thought at that time, some 40 years
- 4 ago, it would be better to refer to the CTR documents
- 5 themselves.
- 6 Q. Sir, I'm asking you what's reported here.
- 7 A. I -- I have --
- 8 Q. Is what I said --
- 9 A. I have acknowledged that that is reported there.
- 10 Q. Is what I said --
- 11 A. There's no argument.
- 12 Q. Is what I said accurate, then, that the TIRC was
- one who thought the method of causation was indirect
- 14 as opposed to direct?
- 15 A. No, sir, that's not accurate. What's accurate
- 16 is what's written here. What the -- what the
- 17 Scientific Advisory Board actually thought and felt
- 18 is more accurately portrayed in their own notes and
- 19 minutes.
- 20 Q. Sir, is it reported in this memorandum that the
- 21 TIRC in '58 believed in the indirect method of
- 22 causation? Is that's what -- is that is what is
- 23 reported?
- 24 A. That is what is reported.
- 25 Q. Thank you.

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- 1 Now when you went to the Scientific Advisory
- 2 Board minutes, do you know who wrote those?
- 3 A. Well I --
- 4 Yes, I know -- I've reviewed some of the minutes
- 5 of prior meetings of the Scientific Advisory Board.

- 6 Q. That's not what I asked. The ones that Mr.
- 7 Weber showed you, do you know who wrote those?
- 8 A. Who wrote them?
- 9 Q. Yes.
- 10 A. Members of the staff of the CTR.
- 11 Q. And do you know if they were reporting the
- 12 indirect method of causation?
- 13 A. I think they -- the minutes speak for
- 14 themselves.
- 15 Q. Now if you look at Exhibit 11028 and you go over
- 16 to page seven, --
- 17 A. Yes
- 18 Q. -- and the first full paragraph starts with the
- 19 word "The group...." Do you see that there, after
- 20 that long continuation paragraph on page six?
- 21 A. Yes.
- 22 Q. "The group at the National Cancer Institute
- 23 despite their lack of conviction of a direct causal
- 24 relationship nevertheless advised that the tobacco
- 25 industry must concern itself permanently with the STIREWALT & ASSOCIATES
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- 1 problem of the biological effects of smoking."
- Remember, we talked about that this morning?
- 3 A. Yes.
- 4 Q. Then it goes on to talk about whether or not
- 5 that type of biological research was being conducted
- 6 in the United States by the industry; correct?
- 7 A. Yes.
- 8 Q. And here's what's reported: "Finally our
- 9 attention was drawn to some of the very real policy
- 10 and public relations problems which might arise if
- 11 the industry was seen to be engaged in biological
- 12 testing. In the U.S.A. medical opinion on the likely
- 13 role of smoking in the causation of lung" --
- "Causation" there isn't in quotes; is it?
- 15 A. No.
- 16 Q. Do you know if they're talking about direct or
- 17 indirect causation?
- 18 A. I don't know.
- 19 Q. Or do you know if they're talking about both?
- 20 A. I don't know.
- 21 Q. Okay. "In the U.S.A. medical opinion on the
- 22 likely role of smoking in the causation of lung
- 23 cancer has not become consolidated to anything like
- 24 the extent to which it has in the U.K. and TIRC is
- 25 very much concerned not to encourage any such

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- 1 consolidation or to do anything which might further
- 2 reduce its degree of freedom to criticize and
- 3 comment. For this reason alone it is improbable that
- 4 TIRC would engage overtly in biological research with
- 5 tobacco smoke." Do you see that?
- 6 A. I see that.
- 7 Q. Now, do you know what position the industry was
- 8 taking with regard to causation in 1958?
- 9 A. No.
- 10 Q. The industry was saying there was no causation;

- 11 weren't they?
- 12 A. Was doing what?
- 13 Q. The industry was saying there was no causation;
- 14 were they not?
- 15 A. I don't know that.
- 16 Q. Well you know they're doing it even today; don't
- 17 you?
- 18 A. You asked me what position the industry was
- 19 taking, and I don't -- I simply don't know.
- 20 Q. Well do you think they were admitting causation
- 21 back in '58 and they're denying it today?
- 22 A. I think the industry, like the rest of us, has
- 23 accepted the -- the statistical relationship and the
- 24 risk factors involved, but there -- we still have
- 25 that question of scientific definition of "cause." STIREWALT & ASSOCIATES
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- 1 Q. That's not what I asked you, sir.
- Were they admitting causation back in 1958 and
- 3 denying it today?
- 4 A. I don't know.
- 5 Q. And you don't know if they are denying or
- 6 admitting causation today; is that your testimony?
- 7 A. I don't know, because we have a difference of
- 8 opinion about the definition.
- 9 Q. Do you know if CTR today, right today, has
- 10 admitted causation?
- 11 A. We don't admit or deny anything. We're trying
- 12 to find scientific answers.
- 13 Q. Now can you direct --
- By the way, I believe you said on direct
- 15 examination that CTR never avoided any type of
- 16 research and nobody ever suggested that; correct?
- 17 A. That's correct.
- 18 Q. It goes all the way back to 1954; correct?
- 19 A. I believe it does. But clearly I was not there
- 20 in 1954.
- 21 Q. Direct your attention to Exhibit 10166.
- 22 A. Excuse me. The number again, please.
- 23 Q. 10166. It's in volume one.
- 24 A. I have that.
- 25 Q. It's a memorandum dated March 31, 1980 to Dr. STIREWALT & ASSOCIATES
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- Alex Spears from Dr. Seligman at Philip Morris, and
- 2 it's on Philip Morris letterhead; correct?
- B A. It is a letter on Philip Morris letterhead, not
- 4 a memorandum.
- 5 Q. Okay.

- 6 MR. CIRESI: We'd offer Exhibit 10166.
 - MR. WEBER: No objection, Your Honor.
- 8 THE COURT: Court will receive 10166.
- 9 BY MR. CIRESI:
- 10 Q. Now sir, do you see that's a letter dated March
- 11 31, 1980 from Dr. Seligman, vice-president, research
- 12 and development, -- that's in the upper left-hand
- 13 corner -- and it's to Dr. Alex Spears of the
- 14 Lorillard Company. Correct?
- 15 A. Correct.

- 16 Q. And there's carbon copies to Mr. Bowling and Dr.
- 17 Osdene. Do you see that down at the bottom?
- 18 A. Yes.
- 19 Q. Do you know who Mr. Bowling is?
- 20 A. Yes. Was.
- 21 Q. Who was he?
- 22 A. He was the vice-president of Philip Morris.
- 23 Q. Okay. And did you know him personally?
- 24 A. Yes.
- 25 Q. Did you ever talk to him about smoking causing STIREWALT & ASSOCIATES
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- 1 lung cancer?
- 2 A. No.
- 3 Q. Did you ever talk to him about trying to avoid
- 4 certain type of research?
- 5 A. No.
- 6 Q. "Dear Alex:
- 7 "Mr. J. C. Bowling of our New York office asked
- 8 that I send you our recommendations for industry
- 9 research which we were -- which we prepared last
- 10 year. To that end, you will find attached a list
- 11 entitled, 'Potential Long-Term Scientific Studies'
- 12 which Dr. Osdene and I generated early last year.
- 13 Additionally, I have added -- I have added a list of
- 14 three subjects which I feel should be avoided.
- 15 "If you have any questions, please let me know."

 16 Do you see that?
- 17 A. I do.
- 18 Q. And can you direct your attention to the third
- 19 page, which is "SUBJECTS TO BE AVOIDED."
- Number one, "Developing new tests for
- 21 carcinogenicity."
- Number two, "Attempt to relate human disease to
- 23 smoking."
- Number three, "Conduct experiments which require
- 25 large doses of carcinogen to show additive effect of STIREWALT & ASSOCIATES
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- 1 smoking." See that?
- 2 A. I do.
- 3 Q. Do you know if this was the subjects which were
- 4 to be avoided by CTR at that time?
- 5 A. This is a letter from an executive of one
- 6 tobacco company to an executive of another. Had no
- 7 impact whatsoever on what our Scientific Advisory
- 8 Board did.
- 9 Q. That's not what I asked you.
- 10 Do you know if this was a letter concerning
- 11 subject matters that should be avoided by the CTR?
- 12 A. I know that this was a letter. This is not in
- 13 the CTR files, had -- had no relationship to CTR
- 14 activities.
- 15 Q. Do you know if it related to CTR activities or
- 16 not? That's all I'm asking.
- 17 A. I know that it did not.
- 18 Q. How do you know that it did not relate to CTR
- 19 activities in 1980? Do you have a letter you can
- 20 provide us to that effect?

- 21 A. Well I think it speaks for itself. This is a
- letter from Dr. Seligman to Dr. Spears. I -- I have
- 23 no idea of the origin of this document, but it
- 24 certainly was not a part of CTR, nor was any of this
- 25 enunciated to CTR, nor would the Scientific Advisory STIREWALT & ASSOCIATES
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- 1 Board have paid any attention to it.
- 2 Q. You weren't there in 1980; were you?
- 3 A. No.
- 4 Q. So you don't know if this was a subject matter
- 5 discussion at CTR; do you, sir? You yourself.
- 6 A. I know that there is -- is no reflection that
- 7 any of these topics were ever avoided by the
- 8 Scientific Advisory Board.
- 9 Q. Maybe you didn't hear my question.
- 10 You don't know if this letter related to
- 11 subjects that were going to be avoided by the CTR.
- 12 You don't know that; do you?
- 13 A. I don't know it by personal experience, but I --
- 14 Q. Thank you.
- 15 A. -- know from review of the documents that none
- 16 of this had any impact on the Scientific Advisory
- 17 Board of the CTR.
- 18 Q. Doctor, you can't tell us the protocol for one
- 19 single study of the CTR. Not one.
- 20 MR. WEBER: Objection, Your Honor, move to
- 21 strike.
- 22 Q. Can you?
- MR. WEBER: It's argumentative and been
- 24 asked and answered.
- THE COURT: It has been asked and answered.

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- 1 Q. Sir, you don't know what subjects were avoided
- 2 or not in 1980 based on your own personal experience;
- 3 do you?
- 4 A. Yes.
- 5 Q. By your own personal experience?
- 6 A. By my own personal review of the activities of
- 7 the Scientific Advisory Board and the research that
- 8 was supported by CTR.
- 9 Q. Can you then provide us with the protocols for
- 10 one study conducted by a grantee of the CTR in detail
- 11 that related to smoking and health? Can you provide
- 12 us with that protocol?
- 13 A. Certainly. I will be glad to provide all of the
- 14 research protocols for all of the studies that have
- 15 been accomplished by CTR.
- 16 Q. Can you testify to one here today?
- 17 A. I -- I cannot testify to the protocol because
- 18 that's a very complex protocol. Scientifically it
- 19 means the outline of a scientific methodology. It
- 20 will usually run to some four or five pages.
- 21 Q. And --
- 22 A. And I can't quote that to you.
- 23 Q. And you have never conducted a survey to see if
- 24 the investigators themselves felt that their research
- 25 related to smoking and health. You've never done

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- 1 that; have you?
- 2 MR. WEBER: Objection, Your Honor, it's
- 3 asked and answered.
- 4 MR. CIRESI: This question was not asked.
- 5 THE COURT: No, I think it's a little
- 6 different question.
- 7 Q. Sir, you have never conducted a survey to see if
- 8 the investigators themselves felt that their research
- 9 which they got money for from CTR related to smoking
- 10 and health; have you?
- 11 A. No. And I'll be glad to tell you the reasons
- 12 that we haven't if you want.
- 13 Q. Mr. Weber can ask you those if he feels those
- 14 are relevant. All right?
- Now you do know that there has been published in
- 16 the medical literature articles relating to what the
- 17 Scientific Advisory Board feels whether their
- 18 research was related to smoking and health; don't
- 19 you?
- 20 MR. WEBER: Let me object, Your Honor. If
- 21 he's going to cross about an article, I think he
- 22 needs to establish under the Rules of Evidence that
- 23 it's authoritative and reliable.
- MR. CIRESI: I'm just asking him if he
- 25 knows, Your Honor.

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- 1 THE COURT: Well does it relate to a
- 2 particular article, counsel?
- 3 BY MR. CIRESI:
- 4 Q. Sir, are you aware of an article by Dr. Warner?
- 5 It's on --
- 6 A. Yes.
- 7 Q. Okay. Was it published in the medical
- 8 literature?
- 9 A. I think so.
- 10 Q. All right. And did that apply to whether or not
- 11 members of the Scientific Advisory Board felt that
- 12 their research related to smoking and health?
- MR. WEBER: Same objection, Your Honor. He
- 14 hasn't established it is a learned treatise or
- 15 authoritative. He didn't ask that.
- 16 THE COURT: Well he says he's familiar with
- 17 it, so I guess he can answer the question.
- 18 Q. Sir, can you answer the question?
- 19 A. What is your last question?
- MR. CIRESI: May I have the question back,
- 21 please, Mr. Stirewalt.
- 22 (Record read by the court reporter.)
- 23 A. There's some confusion there. Scientific
- 24 Advisory Board was not doing research, Scientific
- 25 Advisory Board was evaluating research projects, so STIREWALT & ASSOCIATES
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l their research is not at issue here as to whether it

- 2 was related to smoking or not.
- 3 Q. Did these Scientific Advisory Board members
- 4 relate whether or not the work of the CTR was related
- 5 to smoking or health, do you know? If you don't
- 6 know, just tell us that.
- 7 A. I don't know.
- 8 Q. All right. Now the CTR isn't funding anything
- 9 today; is it?
- 10 A. Oh, yes.
- 11 Q. It is.
- 12 A. Yes.
- 13 Q. Still funding projects?
- 14 A. We're still funding the obligations to which we
- 15 committed prior to last June.
- 16 Q. Oh, prior to last June. But you're not --
- 17 you're no longer funding programs on a going-forward
- 18 basis; are you?
- 19 A. We are not funding any new grants pending the
- 20 outcome of the tobacco legislation.
- 21 Q. And that's because the CTR will be dissolved
- 22 under the pending legislation; correct?
- 23 A. We don't know that.
- 24 Q. That's what's being proposed; correct?
- 25 A. It is a --

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- 1 It was a proposal of the attorneys general.
- 2 Q. Now sir -- and -- strike that.
- 3 And the industry agreed to it; didn't it?
- 4 A. Yes.
- 5 Q. Now the Journal of the American Medical
- 6 Association is a peer-review journal?
- 7 A. Yes.
- 8 Q. It's a premier journal of the American Medical
- 9 Association?
- 10 A. Yes.
- 11 Q. And it's reported on the CTR and its research;
- 12 hasn't it?
- 13 A. Yes.
- 14 Q. You've read it; haven't you?
- 15 A. Yes.
- 16 Q. And it was highly critical; wasn't it, sir?
- 17 A. It was highly biased.
- 18 Q. Well doctor, I'm -- I'm really not here to argue
- 19 with you whether it's biased or not. I just asked
- 20 you whether it was highly critical.
- 21 MR. WEBER: Let me object to the
- 22 commentary, Your Honor.
- 23 THE COURT: Well it certainly was a
- 24 non-responsive answer to the question, so please try
- 25 and respond to the question.

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- 1 MR. WEBER: Your Honor, may I enter another
- 2 objection before further questions are asked with
- 3 respect to this editorial, as to whether the witness
- 4 considers it authoritative or a learned document of
- 5 the type under the rule?
- 6 THE COURT: With regard to the American

```
7
    Medical Association?
8
             MR. WEBER: With regard to the article that
9 he's about -- if -- if in fact he's going to ask
10
    specifics about the article, yes, Your Honor.
              THE COURT: Well let's wait for the
11
12
    question.
    BY MR. CIRESI:
13
    Q. Doctor, may I have an answer to my last
14
15
    question? It was highly critical of the C --
16
    A. Yes.
17 Q. Thank you.
        Did you write a response to the comments in this
    peer-reviewed journal concerning the CTR?
19
20
    A. No.
21
    Q.
         Did anybody direct you to do so?
2.2
    A.
         No.
         Did anyone on behalf of the industry write a
2.3
    Q.
    response to the peer reviewed article in the JAMA --
2.4
25
    in the JAMA journal?
                   STIREWALT & ASSOCIATES
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            RECROSS-EXAMINATION - JAMES F. GLENN
    A. Not to my knowledge.
 1
 2
    Q.
         And JAMA is a peer-reviewed journal; correct?
 3
         Yes.
    Α.
 4
    Ο.
         It's authoritative; correct?
        In some instances.
 5
    Α.
         It's reliable; correct?
 6
    Q.
    A. In most instances.
 7
              MR. CIRESI: Your Honor, we'd offer Exhibit
 8
9
   18986. May I approach, Your Honor?
10
             MR. WEBER: Your Honor, could we have a
    side-bar with respect to this?
11
12
13
14
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               (Side-bar discussion as follows:)
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- 1 BY MR. CIRESI:
- 2 Q. Now doctor, are you aware whether or not the
- 3 American Medical Association has taken a position
- 4 that smoking causes lung cancer?
- 5 A. They did.
- 6 Q. And they have; correct?
- 7 A. Yes.
- 8 Q. And has the American Medical Association ever
- 9 been critical of CTR?
- 10 A. Yes.
- 11 Q. Has it been critical of its research?
- 12 A. Not of the research, of the source of funding.
- 13 Q. Is that the only thing you think the American
- 14 Medical Association has been critical of with regard
- 15 to CTR, just the source of the funding and not its
- 16 research?
- 17 A. I don't know that they've criticized any
- 18 specific research, no.
- 19 Q. You just don't know one way or the other; is
- 20 that what you're saying?
- 21 A. I don't know that they have, no.
- 22 Q. So you don't know one way or the other whether
- 23 they have or haven't; is that a fair statement?
- 24 A. That's fair.
- 25 Q. Now sir, having in mind the fact that you've STIREWALT & ASSOCIATES
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4966

- 1 never had a specific subject-matter discussion with
- 2 any member of the CTR's Scientific Advisory Board as
- 3 to whether smoking causes cancer, you don't know what
- 4 their research shows; do you?
- 5 A. Again, the Scientific Advisory Board, currently
- 6 some 15 individuals, does not do research into
- 7 smoking and health. They evaluate the proposals, the
- 8 applications that we receive requesting funding of
- 9 independent research.
- 10 Q. Well let me take that answer and see if I can
- 11 answer you -- ask you a question in a different way.
- 12 In light of the fact that you've never discussed
- 13 the specific subject matter of whether smoking causes
- 14 cancer, it would be fair to state that when you've
- 15 reviewed these applications for money from
- 16 investigators with the Scientific Advisory Board,
- 17 you've never discussed whether any of those studies
- 18 dealt with whether smoking causes cancer; correct?
- 19 A. No. We've discussed the issues of causation in
- 20 both the scientific and the lay sense as we've
- 21 discussed here, so those discussions have been open
- 22 and frank, and I think there is a general
- 23 understanding among the members of the Scientific
- 24 Advisory Board regarding those issues.
- Q. Do you recall giving your testimony last week, STIREWALT & ASSOCIATES
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- 1 page 4576:
- 2 "Question: That's not what I asked you. That

```
specific subject matter, smoking causing cancer,
    you've never had a specific discussion with any
 4
    member of the board in 11 years; correct?
 5
         "MR. WEBER: Same objection.
          "THE COURT: You may answer.
7
8
         "The answer is no. We -- we haven't addressed
     that specific point."
9
10
         Now did you give those answers to those
11
    questions?
12
    A. I give the same answer. We haven't -- we have
    never raised a question, "Does smoking cause cancer?"
13
    We've talked about causation, we've talked about risk
    factors, we've had in-depth discussions about various
15
16
    aspects of the problem.
17
    Q. Sir --
18
    Α.
         But I've never asked the specific question
19
    that -- that you posed to me.
20
    Q. So you never asked that specific question;
21
    correct?
22 A. No, sir.
23
   Q. And in looking at the funding for all the
24
    projects, you've never asked the specific question of
    any of the Scientific Advisory Board members, when
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            REDIRECT EXAMINATION - JAMES F. GLENN
    looking at applications, will this show whether
     smoking causes lung cancer. You've never had any.
 2
 3
 4
    Q.
         And that's in the entire 11 years; correct?
 5
    A. Yes.
    Q. Now did any of the executives of any of the
 6
    companies in the last 11 years ever ask you that
 7
    specific question, "Have you folks addressed the
 8
    specific issue does smoking cause cancer?" Have they
9
10
    ever asked you that?
              MR. WEBER: Objection, Your Honor, asked
11
12
    and answered.
              THE COURT: It's been asked and answered.
13
14
              MR. CIRESI: I have no further questions.
15
    Thank you, doctor.
             MR. WEBER: Just a very few questions, Dr.
16
17
    Glenn.
18
                        REDIRECT EXAMINATION
19
    BY MR. WEBER:
    Q. With respect to the issue of animal inhalation
20
21
    experiments, do you remember Mr. Ciresi asking you
22
    some questions about that?
23
    A.
         Yes, sir.
    Q. And whether or not lung cancers had been
24
    produced in animal inhalation experiments?
                   STIREWALT & ASSOCIATES
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            REDIRECT EXAMINATION - JAMES F. GLENN
                                                    4969
    A.
         Yes, sir.
 1
         Do you know what the position of the United
    States Surgeon General is with respect to the issue
 4
    of whether animal inhalation experiments have
 5
   produced significant numbers of lung cancers in
    animals?
 7
    A. I do.
```

- 8 Q. What is that position?
- 9 A. The position of the Surgeon General is that lung
- 10 cancer has not been produced in animals by inhalation
- 11 studies.
- 12 Q. And with respect to page 218 of the 1982 Surgeon
- 13 General's report, is this language that which you're
- 14 referring to: "Attempts to induce significant
- 15 numbers of bronchogenic carcinoma in laboratory
- 16 animals were negative in spite of major efforts with
- 17 several species and strains?"
- 18 A. Yes, sir.
- 19 Q. By the way, Mr. Ciresi also asked you some
- 20 questions about the 1964 Surgeon General's report.
- 21 A. Yes.
- 22 Q. At the beginning of the 1964 Surgeon General's
- 23 report, did the Surgeon General's Advisory Committee
- 24 include the Tobacco Industry Research Committee as
- 25 one of the persons and institutions that's thanked STIREWALT & ASSOCIATES
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- 1 for their cooperation?
- 2 A. Yes.
- 3 Q. Did it include Dr. Little?
- 4 A. Yes.
- 5 Q. And did it include Dr. Hockett as well?
- 6 A. Yes.
- 7 Q. On this issue that Mr. Ciresi has asked you
- 8 about, about whether or not there ought to be a
- 9 survey of the grantees as to what their viewpoints
- 10 are with respect to causation and what definition of
- "causation" they use, do you remember those
- 12 questions?
- 13 A. Yes.
- 14 Q. Do you think conducting such a survey would be a
- 15 good or a bad idea?
- 16 A. Oh, I think it would be a disastrous idea. In
- 17 the first place, the grantees might take the position
- 18 that we were asking their opinion about smoking and
- 19 diseases as a basis for whether or not we would award
- 20 funds, and I would be terribly -- I think people
- 21 would be terribly critical of a survey in that
- 22 respect. So I think to maintain independence with
- 23 the investigator, we'd have to avoid such a survey.
- 24 Q. Would such a survey provide scientific
- 25 information?

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- 1 A. No. A survey of that type would depend on
 - how -- how the individual defined the word "cause,"
- 3 so it would be statistically insignificant and
- 4 scientifically inaccurate.
- 5 Q. Now Mr. Ciresi also asked you some questions
- 6 about whether or not you'd ever engaged in any
- 7 discussions regarding taking carcinogens out of
- 8 cigarettes. Do you remember that?
- 9 A. Yes.
- 10 Q. Is CTR allowed to get into product development
- 11 issues?
- 12 A. No, sir. And we have avoided it specifically.

```
Now he also read you a portion -- and I might be
14
    able to put this on the Elmo if you don't remember
15
    it -- where he talked about how TIRC, at least
16
    according to this 1958 memorandum, was reluctant to
    do biological research of tobacco smoke. Do you
17
18
    remember that?
19
    A. I do.
    Q. Has TIRC or CTR done biological research with
20
21
    tobacco smoke since 1958?
22
    A. Yes, sir. In the early days of TIRC a lot of
    biologic studies were accomplished, and as I've
23
    explained to the jury before, the evolution of -- of
24
25
    science in general has dictated that we go down more
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    and more to the molecular, cellular, chemical level.
1
    But in the early days, you know, we supported a great
 3
    deal of so-called biological research, one major
    inhalation program -- several -- several major
 4
     inhalation programs. So biological research was
 5
    certainly prominent in the early days.
 6
7
              MR. WEBER: Thank you very much, Dr. Glenn.
8
    That's all I have.
9
              MR. CIRESI: Just two -- about three
    questions. Deals with the Surgeon General report.
10
    That's -- that's all really I have.
11
              THE COURT: All right.
12
              MR. CIRESI: I'll let them go. That's
13
14
    fine.
15
              THE COURT: Then, doctor, you may step
16
    down, but you are subject to recall.
              THE WITNESS: Thank you, sir.
17
              THE COURT: We'll take a short recess.
18
              THE CLERK: Court stands in recess.
19
20
              (Recess taken.)
              THE CLERK: All rise. Court is again in
21
22 session.
23
              (Jury enters the courtroom.)
24
              THE CLERK: Please be seated.
25
              MR. GARNICK: Your Honor, may we have a
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    brief side bar before we get started with the next
1
 2
    witness?
 3
 4
 5
 6
7
 8
9
10
11
12
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15
16
17
```

18 19 20 21 22 23 24 25	STIREWALT & ASSOCIATES P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1 REDIRECT EXAMINATION - JAMES F. GLENN	
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	(Side-bar discussion as follows:)	1974
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	STIREWALT & ASSOCIATES P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1 REDIRECT EXAMINATION - JAMES F. GLENN	1953 1975

- 1 Q. Can you briefly describe for the court and the
- 2 jury what biostatistics is.
- 3 A. Yes. There's two parts to it, bio and
- 4 statistics, so let me start with statistics. Now
- 5 statistics is a set of principles and methods for
- 6 using quantitative information; that is, numbers, to
- 7 figure out quantities or -- or -- or things of
- 8 interest, to calculate quantities that we're
- 9 interested in about a population of people.
- 10 And bio refers to the application of statistical
- 11 methods to public health or medicine.
- 12 Q. Dr. Zeger, what are your duties and
- 13 responsibilities as chair of the department of
- 14 biostatistics at Johns Hopkins?
- 15 A. Well as chairman of the department of
- 16 biostatistics I'm a faculty member, like the rest of
- 17 my department, and as a faculty member I conduct
- 18 research on public health problems, I conduct
- 19 research on statistical methods, and I teach
- 20 students, medical and public health students as well
- 21 as Ph.D. students in my own department who are
- 22 training to also become I biostatisticians, and as
- 23 chair of the department I'm the administrative
- 24 director of my department and am responsible for the
- 25 running of the department, for hiring new faculty, STIREWALT & ASSOCIATES

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- 1 for the academic programs that we offer, and for
- 2 managing the business of the department as well.
- 3 Q. How many faculty members are in your department?
- 4 A. I believe we currently have 13 tenure-track
- 5 faculty and three others.
- 6 Q. Can you tell us the range of their professional
- 7 training and expertise?
- 8 A. Yes. Nearly all are Ph.D. trained, they're
- 9 mostly trained in biostatistics, we have one faculty
- 10 member who is also a physician, and their expertise
- 11 is in the application of statistical methods to
- 12 public health problems.
- 13 Q. Doctor, do you conduct your own research?
- 14 A. I do.
- 15 Q. And can you tell us the kinds of research that
- 16 you yourself conduct.
- 17 A. Well there's two kinds of research that I do as
- 18 a professor of biostatistics. In the -- in the first
- 19 kind I work with -- I collaborate with the public
- 20 health scientists, with physicians or medical
- 21 researchers, in order to address public health
- 22 questions, to address the solution of public health
- 23 problems, and in those collaborations I represent the
- 24 quantitative expertise and my medical colleagues
- 25 represent the medical or health expertise.

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- 1 And then I do another kind of research as well.
- 2 In the course of my public health collaborations we
- 3 sometimes find opportunities to develop new

- statistical methods, new tools that could be used in
- the public health problem we're working on, but also 5
- could be used by other public health problems -- by 6
- 7 other researchers doing other public health --
- addressing other public health problems. 8
- 9 Ο. What are some of the courses that you teach?
- I teach two kinds of courses. I teach courses 10 Α.
- 11 to physicians and other health scientists, and
- 12 typically those courses are teaching these health
- 13 scientists how to use statistical methods in their
- professional research or practice, and then I teach 14
- courses that are to graduate students training to
- become biostatisticians, and those courses tend to be 16
- 17 more mathematically oriented, more statistical in
- 18 nature.
- 19 Q. Can you identify some of the subject matters of
- 20 those courses?
- 21 A. Yes. The courses that I teach to the physicians
- 22 and other health scientists -- I'm teaching one now
- 23 to the faculty in the medical school of Johns Hopkins
- 24 entitled "Quantitative Methods for Clinical
- 25 Research, " so it's training the -- many of the STIREWALT & ASSOCIATES
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- students who are on the faculty already how to be 1
- better researchers. Or I would teach an introduction
- to biostatistics, which would be a course for people 3
- 4 who are -- for -- for medical scientists or public
- 5 health scientists who are learning how to use
- statistical methods in their work. And then these 6
- other courses that are to our graduate students tend 7
- to be more technical. I teach there how to do
- statistical modeling. I teach --9
- 10 One of them is called "Generalized Linear
- Models" and one is called "Analysis of Longitudinal 11
- Data." All are about statistical models as applied 12
- 13 to biological or public health research.
- 14 Q. How long have you been chair of the department?
- 15 A. I've been chair for two years.
- Doctor, I now want to go over your education. 16
- Where did you obtain your undergraduate degree? 17
- A. At the University of Pennsylvania, which is in 18
- 19 Philadelphia.
- 20 Q. And what was your undergraduate degree in?
- 21 A. My degree was in biology.
- 22 Q. When did you obtain that?
- 23 A. In 1974.
- Q. And did you pursue graduate studies? 24
- 25 A. I did.

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- Q. Where? 1
- 2 At. --Α.
- 3 I first earned a master's degree in the evening
- in mathematics at Drexel University in Philadelphia.
- 5 I was doing that part time while I was working at an
- institute called the Academy of Natural Sciences in 6
- 7 Philadelphia. And then I went back and earned a Ph.D. in statistics from Princeton University.

- 9 Q. When was that?
- 10 A. I earned the Ph.D. in 1982.
- 11 Q. And did you write a thesis?
- 12 A. Yes, I did.
- 13 Q. What was the subject matter of the thesis?
- 14 A. The thesis was addressing -- if you remember
- 15 back to 1982, there was concern about whether spray
- 16 can aerosols were destroying the ozone layer, and at
- 17 the time we didn't have sattelite information, and so
- 18 the thesis was about looking at the ground
- 19 measurement systems we had for looking at
- 20 stratospheric ozone, or the ozone in the -- high up
- 21 in the atmosphere, and seeing whether there was
- 22 evidence of -- of -- of ozone being diminished by
- 23 these spray cans. And so my Ph.D. thesis was using
- 24 that data and developing statistical models to
- 25 address the question of whether the ozone was being STIREWALT & ASSOCIATES
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- 1 depleted or not.
- 2 Q. After you obtained your Ph.D., what did you do?
- 3 A. I took a position as assistant professor at
- 4 Johns Hopkins University in the department of
- 5 biostatistics, the department I'm currently in.
- 6 Q. Was that in 1982?
- 7 A. Yes.
- 8 Q. What were your duties and responsibilities as an
- 9 assistant professor?
- 10 A. Well, from the beginning I was responsible for
- 11 the three activities which I described, for
- 12 collaborating with health scientists in public health
- 13 research, with doing research on developing better
- 14 statistical tools to be used in that research, and in
- 15 doing education of both health professionals and
- 16 statistical graduate students.
- 17 Q. How long were you an assistant professor?
- 18 A. I believe it was four years.
- 19 Q. And what happened after those four years?
- 20 A. I was promoted to a rank called associate
- 21 professor, which is the next rank in the ladder.
- 22 Q. And did your duties and responsibilities change?
- 23 A. It was the same general area of responsibility.
- 24 I -- I -- I began to take on some additional
- 25 responsibilities for academic committees and STIREWALT & ASSOCIATES
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- 1 developing curricula, things like that, but the basic
- 2 areas were the same.
- 3 Q. How long were you an associate professor?
- 4 A. I believe it was five years.
- 5 Q. And then what happened?
- 6 A. And then in 1991 I was promoted to a professor
- 7 in the department of biostatistics.
- 8 Q. Did your duties and responsibilities then
- 9 change?
- 10 A. Same areas, collaboration with health
- 11 scientists, statistical research and teaching, but
- 12 again the -- the responsibilities increased as I
- 13 became older and in the department.

- 14 Q. Did you take on any other positions at Johns
- 15 Hopkins in 1991?
- 16 A. Yes. We -- we had a new dean at Johns Hopkins
- in 1991, and he asked me to be the academic dean for
- 18 the school, which I did for a period of five years.
- 19 Q. And what were your duties and responsibilities
- 20 as academic dean?
- 21 A. I was responsible for all of the academic
- 22 programs for the faculty, students, and all of the
- 23 interactions that they'd had in our teaching programs
- 24 at the Johns Hopkins School of Public Health. It's a
- 25 school of about 250 faculty plus about 1800 students, STIREWALT & ASSOCIATES
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- 1 and we run quite -- several graduate programs which I
 2 was responsible for.
- 3 Q. How long were you academic dean?
- 4 A. For five years.
- 5 Q. And then what happened?
- 6 A. Then I was given the opportunity to be the chair
- 7 of the department of biostatistics, and I -- I took
- 8 that position and have been there since.
- 9 Q. Doctor, have you published in peer-reviewed
- 10 journals?
- 11 A. Yes, I have.
- 12 Q. Can you just describe for us briefly what a
- 13 peer-reviewed journal is.
- 14 A. Yes. A peer-reviewed journal is where you
- 15 submit a paper for publication and the -- there is an
- 16 editorial process where the editor sends out the
- 17 paper to your peers, people who have expertise in the
- 18 topic about which you are writing, and they review
- 19 the papers and make a recommendation back to the
- 20 editor as to whether the paper merits publication or
- 21 not.
- 22 Q. What types of articles have you published in
- 23 peer-reviewed journals?
- 24 A. Well like my research, I -- I publish two kinds
- 25 of articles. In the first case, I and a collaborator STIREWALT & ASSOCIATES
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- 1 with medical scientists or public health scientists,
- and we work on a problem together, it's usually a
- 3 public health problem, they bring the medical
- 4 expertise or the health expertise and I bring the
- 5 quantitative expertise, and together we would write
- 6 an article about the health issue which is being
- 7 addressed. So that's one kind of article that I
- 8 would be a co-author on with other investigators as
 9 well.
- 10 And then the second kind of research I do is
- 11 what I would call biostatistical research. It's in
- 12 trying to new tools, new techniques, new statistical
- 13 models that could be used in public health research
- or in research by others as well.
- 15 Q. Have you written about statistical models to
- 16 address public health questions?
- 17 A. Yes.
- 18 Q. And I have your CV here and I'd like to ask you

- 19 about a couple of articles. The first one is
- 20 entitled "Longitudinal Data Analysis for Discrete and
- 21 Continuous Outcomes." That appeared in the journal
- 22 called Biometrics; is that right?
- 23 A. Yes.
- 24 Q. That was in 1986?
- 25 A. That's correct.

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- 1 Q. And you were one of the authors?
- 2 A. Yes. I was an author with my colleague, Dr.
- 3 Kung-Yee Liang.
- 4 Q. What was the subject matter of that article?
- 5 A. This was a -- an example of one of these papers
- 6 where we were trying to develop new techniques for
- 7 analyzing data, and the -- the need for the new
- 8 techniques arose out of some of the collaborative
- 9 work I had been doing in public health, and in this
- 10 particular paper we were developing statistical
- 11 models that could be applied to data collected by
- 12 following people through time. So these studies are
- 13 called "longitudinal studies," if you follow people
- 14 forward in time. And the methods that were developed
- in that paper were to address data of that kind.
- 16 Q. And did that paper address regression analysis?
- 17 A. Yes, the method -- the methods that were
- 18 developed in that paper are sometimes referred to as
- 19 regression analysis, which just means that you have a
- 20 health outcome that you're interested in, and you're
- 21 interested in how it relates to a variable, like what
- 22 some people call a risk factor, and the studying of
- 23 the relationship is sometimes called regression
- 24 analysis.
- Q. Did that paper receive any awards? STIREWALT & ASSOCIATES
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- 1 A. It did.
- 2 Q. What -- what award did it receive?
- 3 A. It was named by the International Biometrics
- 4 Society and the American Statistical Association as
- 5 the best paper in biometry, in biostatistics of
- 6 that -- of that year.
- 7 Q. Now you've used the term "Biometrics." What
- 8 does that mean?
- 9 A. Yes. Biometrics was the name of the journal,
- 10 $\,$ and it's sort of an old-fashioned word for
- 11 biostatistics. It -- it describes the use of
- 12 statistical reasoning and statistical methods in
- 13 health research or biological research, more
- 14 generally.
- 15 Q. Is that paper still recognized as an important
- 16 contribution?
- 17 A. Yes, I believe so.
- 18 Q. And why is that?
- 19 A. It recently has appeared in a -- a publication
- 20 that -- that presents -- republishes sort of the best
- 21 papers of the -- of the 1980s, and that was one of
- the papers chosen to appear there.
- 23 Q. Now I want to direct your attention to another

- 24 paper on your CV. That one is entitled "Statistical
- 25 Methods for Monitoring the AIDS Epidemic." And that STIREWALT & ASSOCIATES
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- was published in the journal Statistics and Medicine;
- 2 is that right?
- 3 A. I believe so, yes.
- 4 Q. What was the --
- 5 And you were one of the authors?
- 6 A. Yes.
- 7 Q. What was the subject matter of that paper?
- 8 A. This is another example of a statistical paper,
- 9 a paper developing better tools, that grew out of my
- 10 work in a study called the Multi-Center AIDS Cohort
- 11 Study, or MAX, and it was -- it was work that we did
- 12 in order to understand the -- what HI -- what human
- 13 immune deficiency virus was and how the AIDS epidemic
- 14 was growing. And in this particular paper we
- 15 developed regression methods to describe how fast the
- 16 AIDS epidemic was growing in -- in various
- 17 subpopulations of people, looking at people who
- 18 contracted AIDS in different ways, from -- from
- 19 transfusion of blood if they were hemophiliacs, or
- 20 through sexual contacts. And this -- this paper laid
- 21 out a technique for estimating how fast the epidemic
- 22 was growing in these many subgroups.
- 23 Q. And did you use statistical modeling?
- 24 A. Yes.
- 25 Q. Have you also authored a book entitled "Analysis STIREWALT & ASSOCIATES
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- 1 of Longitudinal Data?"
- 2 A. Yes, I have, with co-authors Peter Diggle and
- 3 Kung-Yee Liang.
- 4 Q. Was that published in 1994?
- 5 A. Yes.
- 6 Q. What is the subject matter of that book?
- 7 A. As I said before, a longitudinal studies are
- 8 studies where we follow people forward in time, and
- 9 they are very common in -- in health research, and
- 10 this -- this book laid out a set of regression
- 11 methods for data of that sort.
- 12 Q. You also serve as an editor of peer-reviewed
- 13 journals?
- 14 A. Yes, I do.
- 15 Q. What journals have you served as an editor for?
- 16 A. I served, I think, for 10 or 11 years as
- 17 associate editor of the Journal of the American
- 18 Statistical Association. And I'm on the -- I'm on
- 19 the editorial board of a large publisher of
- 20 statistical books called Springer-Verlag. They
- 21 publish statistics books and mathematics books and
- 22 other scientific books, and I'm on their statistics
- 23 editorial board.
- Q. Do you also serve as a reviewer of papers?
- 25 A. I do.

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- 1 Q. Now what does a reviewer do?
- 2 A. Well a reviewer is the person to whom a journal
- 3 sends a paper that's been submitted for publication,
- 4 and a reviewer is responsible to study the paper and
- 5 to make recommendations to the editor as to whether
- $\ensuremath{\mathsf{6}}$ $\ensuremath{\mathsf{}}$ the paper should be published or not, and also back
- 7 to the author of the paper, you know, in ways that
- 8 the paper might be improved, whether or not it's
- 9 published.
- 10 Q. What journals do you serve as a reviewer for?
- 11 A. I review for most of the major statistics and
- 12 biostatistics journals, Biometrics, Journal of the
- 13 American Statistical Association, and Biometrica,
- 14 Statistics and Medicine, several of them, as well as
- 15 for journals that publish about health issues. So
- 16 they -- they often look for a statistical reviewer as
- 17 well as a health expert to review papers for the --
- 18 from the health literature.
- 19 Q. Have you also been a member of review panels for
- 20 other departments of biostatistics?
- 21 A. Yes. Yes, I have. Many times a -- a -- a dean
- 22 of a school will, every five or six years, bring in a
- 23 few outside experts to review their own department of
- 24 biostatistics. And so, for example, I think -- I
- 25 think it was last year, Harvard University had three STIREWALT & ASSOCIATES
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- of us come and spend a couple of days studying the work of the department of biostatistics at Harvard
- 3 and then to make recommendations to the dean about,
- 4 you know, the quality of the work and how the work
- 5 might be improved.
- 6 Q. Have you served on review panels for other
- 7 institutions in addition to Harvard?
- 8 A. Yes, I have.
- 9 Q. Which ones?
- 10 A. I think the University of Alabama at Birmingham,
- 11 and several -- University of Rochester, North
- 12 Carolina -- University of North Carolina. Several
- 13 others.
- 14 Q. Have you also done work as a scientific reviewer
- 15 for federal agencies?
- 16 A. Yes. The biggest funder of biomedical research
- 17 is the National Institute of Health, and they have a
- 18 peer-review system for grants, and when a grant is
- 19 submitted, they empanel experts in the field and the
- 20 experts review the submitted grants, all of the
- 21 submitted grants, and then make recommendations about
- 22 which ones should be funded. And so I served on
- 23 these review committees of other people's grants.
- 24 Q. You also served on a review committee for the
- 25 Environmental Protection Agency.

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- 1 A. Yes. For many years the Environmental
- 2 Protection Agency also ran its own research program,
- 3 and I was on their scientific review panel.
- 4 Q. Doctor, could you list for us your professional

- 5 memberships?
- 6 A. I'm a member of the International Biometrics
- 7 Society, of the American Statistical Association, of
- 8 the Institute of -- the International Statistical
- 9 Institute, and the Royal Statistical Society of
- 10 England.
- 11 Q. And did you serve as an officer in the
- 12 International Biometrics Society?
- 13 A. Yes. I was in 1995 president of the Eastern
- 14 North American Region of the International Biometrics
- 15 Society.
- 16 Q. Are you also a member of the American Public
- 17 Health Association?
- 18 A. Yes, I am.
- 19 Q. Doctor, I'd like -- excuse me.
- 20 Professor, I'd like to talk about your awards
- 21 now. You -- you mentioned the award that you
- 22 received for your paper. Have you received any other
- 23 awards?
- 24 A. Yes, I have.
- 25 Q. And can you tell us about those.

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- 1 A. I received an award from the American Public
- 2 Health Association called the Spiegelman Award, which
- 3 was in recognition of the best biostatistician under
- 4 the age of 40. I think this was in 1992 or '3 or
- 5 something like that.
- 6 Q. Professor, are you still eligible for that
- 7 award?
- 8 A. No comment.
- 9 Q. And were you also elected a fellow of the
- 10 American Statistical Association?
- 11 A. Yes, I was.
- 12 Q. When was that?
- 13 A. I believe it was last --
- 14 Two years ago.
- 15 Q. And can you tell us what that means?
- 16 A. Well the American Statistical Association I
- 17 think elects approximately one percent of its
- 18 membership to be what are called fellows, perhaps
- 19 gals, but which is a distinction of -- an
- 20 acknowledgment of your contribution to the field of
- 21 statistics.
- 22 Q. And have you received other awards?
- 23 A. Yes, I have.
- 24 Q. Could you tell us about those.
- 25 A. Yes. I recently received an award from Johns STIREWALT & ASSOCIATES
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- 1 Hopkins University for contributions to the
- 2 educational programs of the university, I think in
- 3 recognition of my service as dean.
- 4 Q. You also serve as the scientific advisor to
- 5 private industry?
- 6 A. Yes, I do.
- 7 Q. Can you tell us about that.
- 8 A. I'm a member of the Scientific Advisory Board
- 9 for the Merck Research Laboratory, which is -- Merck

```
is a large pharmaceutical company, and so I am a
11
    member of a board of people who review annually their
    scientific research programs and make recommendations
12
13
    about, you know, where -- what are areas they might
    work in and -- and ways of strengthening their
14
15
    programs.
    Q. Now Dr. Zeger, you -- I'm getting this -- I'll
16
17
    get this title straight.
18
          Professor Zeger, you have briefly described for
19
    us biostatistics. Can you give us a more detailed
20
    explanation of what you mean.
         Yes. Again, the bio part refers to working in
21
    public health, working on public health problems, and
22
23
    statistics is a field that -- that really is a set of
    ideas or principles as well as a set of methods,
24
25
    tools that we use to take quantitative information,
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    numbers, and draw -- draw conclusions about
    substantive questions, about health questions. So if
    I can say that again, statistics is taking -- is a
 4
    set of ideas, a set of methods and principles by
 5
    which we use information, usually numbers, in order
    to calculate and study quantities of interest like
7
    health effects, for example.
         Can you --
8
         Can you give us an example of a statistical
9
10
    principle?
11
    A. Yes. Actually if I could come to the --
    Q. With the court's permission, can Dr. Zeger
12
13
    please come down and use the flip chart.
    A. Yes. When I say a statistical principle,
14
    it's -- it's a little -- there is -- it's basically a
15
    way in which we -- it's a principle by which we
16
17
    operate when we use quantitative information, and the
    one I've just chosen to illustrate this is what
18
19
    some -- many of you perhaps have heard of, which is
20
    called the law of averages. And it's just an example
21
    of a statistical principle.
22
         And to illustrate what the principle is, it's
    easiest to do this with a little experiment. And
23
24
    rather than bringing 20 coins in here and flipping
    them in front of you, I flipped them a couple of days
25
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    ago. I'm just going to write on the board the series
     of heads and tails that I got when I flipped them to
 3
    illustrate this principle.
 4
          So the first flip was a tails, or T, and then
 5
    another tails, and then a heads, and then a tails,
 6
    and then a heads, then a heads, and a heads, and a
 7
    heads, and a tails, and a tails. That was the first
    10. And if I just carry on quickly, heads, tails,
 8
    tails, heads, heads, tails, heads, heads, tails,
9
    heads. I think that's 20. Let me just count. Yes.
10
11
    So it was 20 coin tosses.
12
         And the principles I'm illustrating is the law
13
    of averages. And what the law of averages says is
    that if you're interested in whether this is a fair
```

```
coin or not; that is, of whether about half the time
16
    the coin will give heads and half the time it will
17
    give tails, we can use this quantity -- this
18
     information, the results of this little experiment
    where we flipped a coin 20 times to -- to see what it
19
20
    says about that, whether or not this is a fair coin.
    And if we look, we can count the numbers of heads,
21
    one, two, three, four, five, six, seven, eight, nine,
22
    10 -- there were 11 heads out of 20 coin tosses, and
23
24
     so it came up heads 55 percent of the time.
25
         Now if we were interested in knowing the
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1
    probability of getting ahead, you know, 55 percent is
    a pretty good estimate, and what the law of averages
 2.
    tells us -- and it's an example of a statistical
 3
    principle -- that if you flip the coin many times,
 5
    keep flipping lots of times and then just count the
    proportion of heads, the percentage of heads, that
 6
    the more times you toss, the closer the proportion of
 7
    heads will come to the true value, which for a fair
 8
9
    coin is 50 percent. So tossing 20 coins, we got the
    observed proportion of heads, 55 percent. But the
10
11
    law of averages says that if you flip many, many,
12
    many times, hundreds of times, that the observed
    proportion would get closer and closer to the true
13
    value; namely, for a fair coin, 50 percent. So
14
15
    that's an example of a statistical principle.
16
    Q. Doctor, can you pick a subgroup and tell us what
17
    that subgroup tells us about the law of averages and
18
    whether or not this is a fair coin.
    A. Well I -- I wrote down 20, the results of 20
19
    tosses. I could have only done, say, three or four,
20
21
    so let me just take the first four, for example. And
22
    in the first four we got tails, tails, heads, tails.
    And if that's all we had done, we would have had what
23
    fraction of heads, what percentage of heads? Only 25
24
2.5
    percent, one out of four or 25 percent. And what the
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 1
    law of averages tells us, that if you only have a few
 2.
    tosses, you -- you won't necessarily come as close to
    the true value, the true proportion of heads, as if
 3
    you have many, many tosses. So by tossing more
 5
    times, the law of average tells us we get closer to
 6
     true percentage of heads.
 7
         So looking at four will give you a less-precise
 8
    estimate of the true probability of heads than
9
    looking at 20.
10
    Q. Could you pick another subgroup, perhaps the
11
    four heads.
12
        Well the other thing to mention is when talking
13
    about the law of averages is, you know, when I look
     at just the first four, I get quite far away from the
14
    true value. The other thing sometimes we're tempted
15
16
    to do is to look along a sequence, and say, oh, look
17
    at this, heads, heads, heads. We should -- we
18
     should say it's a hundred percent chance of getting a
19
    head. That is to say the law of average tells us if
```

- 20 you look at all of the information and there's enough
- 21 information, it will get close to the true
- 22 probability of a head. But if you search
- 23 purposefully for heads, okay, for sequence of heads
- 24 and then say aha, see, I have four in a row, that
- 25 must mean the probability of a head is a hundred STIREWALT & ASSOCIATES
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- l percent. You can get very far from what the truth is. Okay?
- 3 So the law of averages is just an example of a 4 statistical principle, and it's the kind of thing we 5 use in our work every day.
- 6 Q. Okay, thank you. Resume your place on the 7 stand.
- Now you mentioned that bio was also a part of the word biostatistics. Could you tell us more about that, please.
- 11 A. Yes. Well bio comes from biology, but these
- 12 days the -- because medical research has become such
- 13 a large area of research, most biostatisticians work
- 14 on public health or medical problems, so there are
- 15 still biostatisticians who work more on biological
- 16 problems outside of medicine or public health, but I
- 17 work in public health and most biostatisticians do as
- 18 well.
- 19 Q. Now what do you mean by "public health?"
- 20 A. The word "public health" really refers to
- 21 exactly what it says, it's the health of the public.
- 22 Public health is about how to maximize the health of
- 23 populations of people, and it's a little bit
- 24 different than medicine. I like to think that public
- 25 health includes medicine as a special case. Medicine STIREWALT & ASSOCIATES
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- 1 is about individuals and the treatment of their
- disease; public health is about the health of the
- 3 population, which obviously includes the health of
- 4 individuals and treatment -- developing better
- 5 treatments, but it focuses on populations as opposed
- 6 to just having to worry about one individual.
- $7\,$ Q. Now as a biostatistician, what do you do
- 8 specifically?
- 9 A. Well I do the three things I mentioned earlier,
- 10 I collaborate in addressing public health problems,
- 11 I -- I do statistical research trying to understand
- 12 the principles and the methods used in public health
- 13 research, and I also teach.
- 14 Q. Now what do you mean by "collaboration?"
- 15 A. Well in order for --
- In order to do public health research, you need
- 17 teams of individuals with different sorts of skills,
- 18 and so I'm often a member of a team of individuals
- 19 that would include a health scientist, like a
- 20 physician or a biochemist or a person who is
- 21 knowledgeable about human health and disease, but --
- 22 but what I bring to the collaboration is expertise in
- 23 quantitative sciences, in the use of statistics in --
- 24 in -- in this sort of research endeavor. So

- 25 collaboration, what I mean is there are teams of STIREWALT & ASSOCIATES
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- individuals who bring different skills, work together
- 2 to solve a public health problem.
 3 Q. What if any part of your training assists you in
- 4 communicating with these other health scientists,
- 5 professor?
- 6 A. Well to be an effective biostatistician, you
- 7 have to have expertise in statistics, but you also
- 8 have to have a working knowledge of public health or
- 9 medicine so that you can communicate effectively with
- 10 the public health scientist with whom you're
- 11 collaborating.
- 12 Q. How important is collaboration?
- 13 A. I think to make a meaningful contribution to
- 14 solving a public health problem, you need people of
- 15 different skills, so I would say collaboration is
- 16 essential in order to -- to make a contribution to
- 17 solving a health issue -- health problem, and
- 18 certainly it is for a statistician. A statistician
- 19 working on a health problem would be lost without
- working on a hearth problem would be lost without
- 20 a -- a medical scientist or health scientist who's
- 21 knowledgeable in that particular problem.
- 22 Q. How does collaboration work generally?
- 23 A. Well typically what you would do in a
- 24 collaborative project is you -- the team individuals
- 25 would come together, you would frame the questions STIREWALT & ASSOCIATES
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- 1 you're going to address, and you would then, you
 - know, meet regularly every week, every third day
- 3 and -- and -- and -- and discuss progress that's been
- 4 made and what the next step should be. People would
- 5 take those steps, and you would continually meet and
- 6 work together, and eventually, once you had results,
- 7 would write papers together for the published -- for
- 8 the peer-reviewed literature.
- 9 Q. Now are there examples of collaboration with
- 10 health scientists on your CV?
- 11 A. Yes. As I said, I spend a considerable part of
- 12 my time on such collaborations.
- 13 Q. Let me ask you about a couple of articles. One
- 14 is entitled "AZT Used in AIDS for HIV1 Seropositive
- 15 Homosexual Men, 1987 to 1989," that appeared in the
- Journal of AIDS. You were one of the authors of that paper?
- 18 A. Yes, yes, that was --
- 19 This is an example of a paper where I was
- 20 collaborating with a physician and epidemiologist,
- 21 Dr. Neil Graham, who at the time was at Johns Hopkins
- 22 University, and with several other physicians and
- 23 empidemiologists at institutions across the country.
- 24 And this was a paper that came out of a Multi-Center
- 25 AIDS Cohort Study which I mentioned previously. That STIREWALT & ASSOCIATES
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- 1 study was started by the National Institute of Health
- 2 in 1983. At the time we knew that gay and bisexual
- 3 men were becoming sick from very rare cancers and
- 4 infections, so we knew that their immune system
- 5 wasn't working right, but we didn't know at the time
- 6 about the virus, the human immune deficiency virus.
- 7 That hadn't been discovered yet. And the National
- 8 Institute of Health formed this study in order to try
- 9 to figure out what was going on, why were these men
- 10 becoming sick, and what were the factors that
- 10 becoming sick, and what were the factors th
- 11 influenced who got sick.
- 12 And so this particular paper came a little bit
- 13 later. It was back -- it was, I think, in about 1987
- or so, 1988, and it was after the first treatment for
- 15 AIDS called AZT had been discovered and -- and
- 16 licensed, and this paper was trying to look at who
- 17 gets AZT and whether it's actually being used in --
- in the population of infected men who were entitled
- 19 to get it, and what the barriers were to their
- 20 getting AZT to which they were entitled.
- 21 Q. Now what did the health scientist, Dr. Graham,
- 22 contribute?
- 23 A. Well Dr. -- Dr. Graham is an AIDS specialist, he
- 24 treated AIDS patients and was also trained in
- 25 epidemiology, and so he -- he identified what the STIREWALT & ASSOCIATES
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- 1 important question was and -- and also what the
- 2 important data was. And we worked together on using
- 3 that information, using that data to address the
- 4 question of who gets AZT and why, what are the
- 5 factors that influence who gets it.
- 6 Q. What did you contribute, Professor Zeger?
 - A. Well this -- this was an example of a -- a study
- 8 in which we followed people through time, and so I
- 9 contributed those methods that I had mentioned
- 10 earlier, statistical methods, modeling techniques for
- 11 longitudinal data.

7

- 12 Q. How did the collaboration work between you and
- 13 the other health scientist?
- 14 A. Well we would meet -- I think back then we were
- 15 meeting several times a week. We had a programmer
- 16 who was working with us, and we would look at the
- 17 information, make some decisions, make some tables,
- 18 study -- study the data, ask, you know, follow-up
- 19 questions, work further. And -- and over a period,
- 20 it must have been six months to a year, we developed
- 21 the -- the study -- the -- the analyses of the
- 22 Multi-Center AIDS Cohort Study data that led to that
- 23 paper and a few others.
- Q. Let me ask you about another paper on your CV.
- 25 That one is entitled "Statistical Models of Air STIREWALT & ASSOCIATES
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- 1 Pollution and Mortality in Philadelphia," published
- 2 in the American Journal of Epidemiology. Could you
- 3 tell me whether that's another example of the
- 4 collaborative effort?
- 5 A. Yes. This is again a paper that was asking a --

```
addressing a public health question. The question
 6
 7
    arose not too long ago when it was noticed that if
    you look at daily fluctuations in the numbers of
8
9
    people who die in American cities, that if you tend
    to have a high pollution day, the next day you get
10
11
    more deaths than you did if you didn't have a high
    pollution day. And this was quite a surprising
12
13
    finding because we've done a lot of good work to
    reduce the pollution levels in American cities, and
14
15
    the fact that there's still a potential association
    between current levels and mortality was somewhat
16
17
    surprising.
         So this was a study that was undertaken, led by
18
19
    Dr. Jonathan Samet, who testified here, my colleague
20
    from Johns Hopkins University, and -- and I
21
    participated as the biostatistician. There was
22
    another biostatistician who -- who participated. And
23
    we -- we've been working now for about 18 months on
24
    this project to try to understand what it is about
25
    the air pollution that might -- might cause increased
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 1
    mortality.
         What is Dr. Samet's background and training?
         Well Dr. -- in this --
 3
         Dr. Samet is an epidemiologist and a physician,
 4
    a pulmonary physician, so he has expertise in the
 5
 6
    human lung. And this was a study of potential -- of
 7
    air pollution as a potential risk factor for -- for
    the functioning of the lung.
 8
9
    Q. And what did Dr. Samet contribute to this study?
    A. Well Dr. Samet was the medical expert. Rather
10
11
    than just looking at the data, he would help us frame
12
    the question from a medical perspective, so that when
    we did analysis, we addressed the relevant medical
13
    question. And he and I have collaborated with a
14
    third person, as I had indicated.
15
16
    Q. And what did you contribute?
17
    A. Well again, this was a fairly complicated data
    set. There was lots of information. The particular
18
    paper you referred to was data from Philadelphia. We
19
20
    used Philadelphia because we had about 5,000
21
    consecutive days of mortality information, and air
22
    pollution information, and lots of different air
    pollutants, too, not just one or two, so my
23
24
    contribution was to -- was to figure out how to do
    statistical modeling to address the question of
25
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 1
    whether there was an association between air
    pollution and mortality.
    Q. How did the collaboration work?
 3
        Well just like the first example, we -- you
    know, we would meet two, three times a week, we
 5
    had -- we also had programming assistants, and we
 6
 7
    would take the -- the data, the data that had been
```

available and -- and work together to try to

understand the -- the evidence and the data about the

association between pollution levels and mortality.

http://legacy.library.ucsf@dw/tid/zstp@5a00/pdfndustrydocuments.ucsf.edu/docs/kxxd0001

8 9

- 11 But it involved regular meetings, and it's been going
- 12 on now for about 18 months. And that was one of our
- 13 early papers from the effort.
- 14 Q. Let me ask you about another paper on your CV,
- 15 this one is entitled "Passive Smoking, Air Pollution
- 16 And Acute Respiratory Symptoms in a Diary Study of
- 17 Student Nurses." Can you tell me whether that's an
- 18 example of a collaborative effort?
- 19 A. Yes, it is. It's another example. And in this
- 20 case my collaborator is now a professor at Harvard
- 21 University School of Public Health, his name is Joel
- 22 Schwartz. At the time I was working with him he was
- 23 a senior scientist at the Environmental Protection
- 24 Agency. And he had this data set, this really unique
- 25 data set where nurses agreed to keep daily records of STIREWALT & ASSOCIATES
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- their respiratory symptoms, whether they had a fever,
- whether they were coughing, phlegm, other conditions
- 3 like that. So you had every day, filled out all the
- 4 forms, of what their respiratory conditions were.
- 5 And in addition there was information about their
- 6 smoking, about their roommate's smoking, and about
- 7 the air pollution levels around the nursing school.
- $8\,$ $\,$ And there was, I think, about 200 nurses who agreed
- 9 to do this for quite an extended period of time, so
- 10 it was an invaluable source of information to try to
- 11 understand, you know, the roles of smoking,
- 12 environmental tobacco smoke and air pollution in --
- in causing respiratory symptoms, coughs and -- not --
- 14 not serious disease, but -- but -- but diminished
- 15 health.
- 16 Q. What did Dr. Schwartz contribute?
- 17 A. Well Dr. Schwartz is an air pollution specialist
- 18 and had done numerous studies previously looking at
- 19 the health effects of air pollution, and so he -- he
- $20\,$ $\,$ was the substantive expert, the pollution health
- 21 expert. And I again brought the expertise in
- 22 quantitative methods.
- 23 Q. And did this --
- 24 Did the quantitative methods include statistical
- 25 models?

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- A. Yes. So we did statistical modeling of that
- 2 data to address the question I described.
- Q. Now we've talked about statistical models
- 4 generally. Can -- can you tell us what a statistical
- 5 model is?
- 6 A. Yes. That word seems to be used for just about
- 7 everything. A statistical model -- let's start with
- 8 model, because we all know what we mean by a model.
- 9 A model is an approximation to reality. It's -- it's
- 10 an approximation to something. So the simplest
- 11 example is a model airplane. It's not -- it's not a
- real airplane in the sense that I can't get in a
- 13 model airplane and fly back to Baltimore, so it's not
- 14 a real airplane, but it's -- it's an approximation of
- 15 an airplane. It's built to look like the airplane.

```
And it's a -- in -- in many situations it's a tool.
     If you think about how we build airplanes today, how
17
    you design and build airplanes today, in fact I saw a
18
19
     television show where -- where -- where they
     described the building of the Boeing 777. They built
20
21
     lots of model airplanes and actually had done some --
     some statistical models as well, but lots of model
22
23
     airplanes, physical model airplanes in order to
     figure out how the real airplane would fly. So if
24
    you wanted to know something about how air might flow
25
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     across the wings of an airplane, whether it would
 2
     have very much turbulence or not, it would be a
     stable airplane or not, how you should design the
 3
    wings so to minimize the turbulence, well you might
 4
    build a model airplane and put it in a wind tunnel
 6
     and then watch to see how the airplane performs.
 7
     It's not a real airplane, but it's an approximation
     to the real airplane, and it's a tool that we use in
 8
     studying the real airplane.
 9
10
          So that's what I mean by a model. It's an
11
     approximation to reality. It's a tool that we use to
12
     study something.
          Now what's a statistical model? Well if we
13
     follow this -- this model airplane a little bit
14
15
    further, suppose we were going to build a real
16
     airplane but we started with a physical model in
17
     order to study the turbulence around the wings. We
     might be considering lots of different wing designs,
18
     might be slightly different angles or slightly
19
     different shapes. And what we might do is -- is, in
20
    the model airplane, vary the shape of the wing a
21
22
    little bit, and for each wing shape actually measure,
23
     quantitatively measure the degree of turbulence, so
    for all the different wing shapes we built models
24
    for, we would have a measure of the degree of
25
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     turbulence. Then a statistical model would take
 2
     those quantitative -- that quantitative information,
     the shape, that describes the shape of the wing and
 3
    describes how much turbulence there was, and try to
 4
 5
     look to see how these things are associated with one
 6
     another.
 7
          Why would we do that? Because we want to build
 8
     a wing for the real airplane that has a minimum
     amount of turbulence. So that would be an example of
 9
10
     a statistical model analogous to the physical model
11
     of the airplane which I described.
     Q. You used the term quantitative information.
13
     What -- what do you mean by that?
14
     A. I basically mean numbers. You know, if you're
     trying to measure turbulence, there -- there --
15
     there's sort of a measuring device which one might
16
17
     use -- I'm not expert in this, but -- but I'm -- I'm
18
     saying that what you'd do is you would measure a
19
     number that would characterize the nature of the
20
     turbulence and -- and then also numbers to represent
```

- 21 the shape of the wing, and then you'd study using the
- 22 numbers how the shape of the wing was related to the
- 23 degree of turbulence.
- 24 Q. Taking your example, doctor, once the
- 25 statistician took these measurements, what if any STIREWALT & ASSOCIATES
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- 1 assistance would the statistician seek then?
- 2 A. Well, you wouldn't make very much progress, I
- 3 don't think, unless the statistician was
- 4 collaborating with, in this case, an aeronautical
- 5 engineer, somebody who knew about wings and
- 6 turbulence. You wouldn't make very much progress if
- 7 you just worked in a vacuum.
- 8 Q. Now have you yourself said that statistical
- 9 models for data are never true?
- 10 A. Yes, I --
- 11 It's sort of like saying you can't fly in a
- 12 model airplane. They're -- they're approximations to
- 13 reality. They're tools that we use in order to
- 14 address particular questions.
- 15 Q. Have you prepared an example of a statistical
- 16 model?
- 17 A. Yes, I have.
- 18 Q. I want to direct your attention now to Trial
- 19 Exhibit 30176. And is that an example of a
- 20 statistical model?
- 21 A. I'm sorry, could you repeat the number again?
- 22 Q. Yes, 30176. That's in the book in front of you.
- MR. HAMLIN: Your Honor, we have placed
- 24 your demonstrative book to your right.
- 25 A. Yes, I have it.

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5014

- 1 Q. Now is that an example of a statistical model?
- 2 A. Yes, it is.
- 3 Q. And this was prepared by you?
- 4 A. Yes.
- 5 MR. HAMLIN: Your Honor, we offer Trial
- 6 Exhibit 30176 for illustrative purposes.
 - MR. GARNICK: No objection.
- 8 MR. HAMLIN: Can we have that on the Elmo,
- 9 please.

- THE COURT: The court will receive 30176
- 11 for illustrative purposes.
- 12 BY MR. HAMLIN:
- 13 Q. Doctor, can you tell us what this statistical
- 14 model is.
- 15 A. Can I just come down here? It will be easier.
- 16 This is just a -- a simple what -- what we call
- in the jargon a two-by-two table. It's not a very
- complicated thing. It's two because there are two rows and two columns, two by two. And -- and it's a
- 20 statistical model in the sense that it has
- 21 quantitative information, numbers, you see here 25.
- 22 That helps us understand how in this case the time
- 23 needed to drive to the airport depends on some
- factors that we might want to take into account when we're planning our trip to the airport; namely, where

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- 1 are you leaving from, either downtown Minneapolis or
- 2 here at the courtroom in downtown St. Paul, and when
- 3 are you leaving, either going at mid-day when it's
- 4 not rush-hour, or traveling during rush-hour. And
- 5 what this table shows is the average time it takes to
- 6 get from each of these locations, here downtown
- 7 Minneapolis at mid-day, 25 minutes. Okay? And
- 8 downtown St. Paul at mid-day, 15 minutes. It takes
- 9 less time. And during rush-hour, downtown
- 10 Minneapolis to the airport, 45 minutes. So it's
- 11 25 -- 20 minutes longer during rush-hour than during
- 12 mid-day, and from downtown, 35 minutes during
- 13 rush-hour, again, 20 minutes longer.

So this is an example of using quantitative information to address a question how long does it typically take to get to the airport. And we have two factors, where are you leaving from, and what

18 time are you leaving, that we might take into account

19 when we plan a trip to the airport.

Now all of us go to the airport all the time to pick up a friend or perhaps we work out there or

perhaps we are even lucky enough to take a flight,

and when we think about when we're going to leave for

24 the airport, we all go through these sorts of

25 calculations. We all sort of think, well, I'm going STIREWALT & ASSOCIATES

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to be downtown in Minneapolis, so I better leave a

2 little longer, and I'm not going to be able to get

out until 4:00 o'clock, so I need to leave longer

yet. So we're -- we're -- we're always thinking

about how a particular outcome, here time to the

6 airport, depends upon factors which we think may

influence it.

14 15

16

17

3

5

7

15

8 This is just an example of a statistical model.

9 It's a tool. It isn't exactly right. You don't

10 always take 15 minutes. Although when I -- I got

11 this table, consulting some of the local experts, and

12 when I did come from the airport a couple days ago, I

13 did take exactly 15 minutes from the airport to

14 downtown St. Paul.

THE COURT: Was that in a cab?

16 (Laughter.)

17 THE WITNESS: It was in a cab, yes. It

18 took me 15 minutes to get the cab.

19 A. So it isn't always that way. Sometimes it's a

20 little bit longer, sometime it's a little bit more.

21 And there are certainly other factors that aren't

22 listed here. I mean a truck that's, you know, broken

23 down in the right-hand lane, there are some factors

that can also influence which aren't here.

25 Nevertheless, this is -- this is a useful -- useful STIREWALT & ASSOCIATES

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1 thing to know. If I had never been to this area and

```
needed to plan a trip to the airport, I would
    certainly start here.
 3
         And the other point about this little example,
 4
 5
    it's an example of a statistical model, it has
    quantitative information and how that quantitative
 6
7
    information depends on factors, but it's something we
    always do. All of us do it every day. And I've just
8
    chosen one example, but if you think in your own
9
10
    mind, there are many others -- many other examples
11
    where we take quantitative information and make
    decisions using that information and how that
12
    information depends on certain factors.
13
    Q. Now can this statistical model also be expressed
14
15
    as a formula?
16
    Α.
        Yes.
         And have you prepared an exhibit showing that
17
    Q.
    that -- that formula?
18
19
    A. Yes, I have.
20
    Q. I'd like you to turn to Trial Exhibit 30175, and
21 is that entitled "Statistical Models can be Expressed
22
    as Formulas?"
23
    A. Yes, it is.
    Q.
24
         It was prepared at your direction?
25
    A. Yes.
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              MR. HAMLIN: Your Honor, plaintiffs offer
1
 2
    Trial Exhibit 30175 for illustrative purposes.
 3
              MR. GARNICK: No objection.
              THE COURT: Court will receive 30175.
 4
5
              MR. HAMLIN: Can we have that on the Elmo,
 6
    please.
7
   BY MR. HAMLIN:
    Q. Doctor, could you tell us what we see on this
8
9
    exhibit?
    A. Yes. This -- the purpose of preparing this
10
11
    exhibit is to show that that information which we
12
    were just looking at, the kind of information we use
    every day that helps us make decisions, that
    information can be expressed not only in a little
14
    table but also as a formula, and this is an
15
16
    illustration just to make that point.
17
         So what's now displayed on the Elmo is the
18
    original table with the -- the numbers we've already
19
    talked about, the times to the airport, and I've just
20
    rewritten those four numbers, 25, 50, 45, 35, in a
21
    formula. Okay? Let's just see. And sometimes it's
22
    a little bit off-putting, but let's just see what it
23
    says.
24
         The formula says if you want to know the time in
25
    minutes to the airport, what you should do is start
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    with 15 minutes. Okay? But if you're going from
    downtown Minneapolis you should add 10 minutes, and
 2
 3
    if you're going during rush-hour you should add 20
 4 minutes.
         So let's see if this formula works. And it's --
    all a formula means is it has a left-hand side, the
```

```
thing you're interested in, time in minutes, and that
    says that equals some factors. All right? And you
 8
    just add up the numbers to get what you -- to get
9
10
    the -- the value of interest. So let's see if the
    formula works. Let's start by a trip from St. Paul
11
    during mid-day. We know that takes an average 15
12
    minutes according to this table. So the formula says
13
14
    the time is 15 minutes, add 10 if you're going from
    Minneapolis. Well we're not going from Minneapolis,
15
    we're going from St. Paul, so don't add 10. Okay?
16
    And if you're going during rush-hour, add 20. Well
17
    we're not going during rush-hour, we're going to
19
    mid-day, so we are not going to add 20, so we end up
20
    with 15. To the formula reproduces the 15 in the
21
    table.
2.2
         What if we want to go from downtown Minneapolis
23
    during the day? We start with 15. It says add 10 if
24
    you're in downtown Minneapolis, so yes, it is. So we
25
    add 10, we get 25. Are we going during rush-hour?
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    No. So we don't do that. So we end up with 15, plus
 1
 2
    10, which is 25, so that's exactly what the table
 3
         Let's just do one more to make sure we get that
 4
 5
    right. Let's do downtown Minneapolis during
    rush-hour. It says 15 plus 10 from Minneapolis, well
 6
 7
    it is, so that's 25, plus 20 if during rush-hour, it
    is rush-hour, so we have 15 plus 10 plus 20 which is
 8
    45, which is exactly what the table says.
9
10
         Trust me, it works for the last one as well.
         So this is just an example of taking the
11
     information in the table, which describes how time to
12
13
    the airport depends on some factors, where you leave
14
    from and what time you go, and putting it in terms of
    a formula. And formulas are convenient because
15
16
    they're the kinds -- that's -- that's what
17
    we can use if we want to make more complicated
    calculations with -- with more factors that we want
19
    to take into account, and they're also desirable
    because we can do our computing in -- we can do our
20
21
    calculations using computers if we can make these
    tables into formulas.
22
23
         And here just to illustrate the idea of taking
24
    something else into account, we have another -- we're
25
    adding another four minutes or every inch of snow in
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                                                    5021
    the previous 24 hours, so that might be an example of
 1
    another factor that you might use to refine your
    estimate of time to the airport.
    Q. Doctor, what if any relationship do statistical
 4
    models have to the real-world events that they
 5
 6
    purport to measure?
    A. Well statistical models are -- are tools for
 7
 8
    calculating quantities of interest in a -- in those
   things we're interested -- those quantities we're
 9
10 interested. So here was an example of -- of a
    statistical model that would help us make a decision
11
```

- 12 about going -- going to the airport at the
- 13 appropriate time.
- 14 Q. Are these models perfect --
- 15 A. No.
- 16 Q. -- in terms of their predictive ability?
- 17 A. No. Obviously everybody understands that the
- 18 time it takes you to get to the airport varies. You
- 19 can't predict it exactly. On the other hand, this is
- 20 an approximation and it's useful. That's -- that's
- 21 the thing. If I were -- if -- if I were to come to
- 22 town now knowing the area and had to plan a cab trip
- 23 to the airport and I said to something I'm going to
- 24 be leaving from downtown St. Paul, it's not going to
- $25\,$ $\,$ be rush-hour, and they said well gee, I can't tell
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- you because I don't know whether there's a pot hole
- out in the highway and I don't know whether such a
- 3 road has, your know, been closed last week and I
- 4 don't know if it's wet. They tell you all the many,
- $\,\,$ 5 $\,\,$ many things that, yes, do influence the time to the
- 6 airport. Well that wouldn't be very helpful to me.
- 7 If they gave me, you know, their best estimate based
- 8 upon perhaps their -- their real experience, that
- 9 would be helpful.
- 10 So the point is models are approximations.
- 11 They're not exactly true. But they're useful, and we
- 12 rely upon them every day for decisions we all make.
- 13 Q. Dr. Zeger, were you retained in this case to
- 14 estimate the amount of health-care costs paid by the
- 15 state of Minnesota and Blue Cross Blue Shield of
- 16 Minnesota to treat diseases and conditions caused by
- 17 smoking, made worse by smoking, or made more
- 18 expensive to treat by smoking?
- 19 A. Yes, I was.
- 20 Q. And what was the time period that you were asked
- 21 to assess?
- 22 A. From 1978 to 1996.
- 23 Q. Now what are these health-care costs called?
- 24 A. We call them smoking-attributable expenditures.
- 25 Smoking-attributable expenditures.

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- Q. Have you reviewed the trial testimony of Dr.
- 2 Jonathan Samet in this case?
- 3 A. Yes.
- 4 Q. And are you relying on it, in part, for your
- 5 opinions in this case?
- 6 A. Yes.
- 7 Q. What if any information has Dr. Samet provided
- 8 to you regarding this definition of
- 9 smoking-attributable expenditures?
- 10 Perhaps you could use the flip chart to answer
- 11 that question, with the court's permission.
- 12 A. This problem is an example of a public health
- 13 problem. And as I illustrated, I think, with the
- 14 previous comments, in order to work effectively on a
- public health problem, you need a collaborative team, and you need experts certainly in public health as

- 17 well as in -- in statistical modeling. And so --18 excuse me.
- 19 So in order to estimate smoking-attributable
- 20 expenditures, which I'll abbreviate if you don't
- 21
- 2.2 Q. And what do you mean by "expenditures?"
- Dollars, basically, dollars expended for 23 Α.
- 24 smoking-attributable treatment.
- In order to estimate this, you need to -- you 25 STIREWALT & ASSOCIATES
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- need to start with a -- a medical model for how the 1 2 world works, and that's what Dr. Samet provided us.
- 3 And basically it was that smoking causes disease, and
- disease results -- excuse me, disease results in 4
- 5 expenditures, in additional expenditures.
- Thank you. 6
- 7 Did you work with others in this project,
- 8 Professor Zeger?
- 9 A. Yes.
- And -- and with whom did you work? 10 Ο.
- 11 A. Well in addition to Dr. Samet, I worked with two
- others, Dr. Len Miller, who's a health economist at 12
- 13 the University of California at Berkeley, and also
- with Dr. Timothy Wyant, who's a Ph.D. biostatistician 14
- trained at Johns Hopkins University. 15
- Q. Now what was Dr. Samet's role in this effort? 16
- 17 Well Dr. Samet, as I said, he was the medical
- 18 expert in our team. He laid the medical foundation
- 19 for everything we did. And I basically described it
- 20 there, that smoking causes disease, which results in
- additional expenditures. So that -- that was the 21
- first thing. He -- he built the -- you could think 2.2
- 23 he laid the foundation on which we built our
- 24 calculations.
- Q. Did he provide screens as well?

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- 1 Α. Yes.
- 2 Could you tell us about that.
- 3 Α. Yes. As -- as I'll describe, we -- we used
- 4 enormous amounts of information on health-care
- expenditures for citizens of Minnesota, and Dr. Samet 5
- helped us assure that the people we identified as --
- 7 as having smoking-attributable diseases actually had
- 8 those diseases.
- Q. And did Dr. Samet provide you with the 9
- conceptual structure of the model? 10
- A. Yes, that's -- that's what I -- that's really 11
- 12 what I described here. We built the model on a
- 13 framework which says smoking causes disease which
- 14 results in expenditures, and so we focused on data
- for smoking, disease and expenditures. 15
- 16 And did Dr. Samet discuss with you studies in
- 17 epidemiology?
- 18 A. Yes. As I said, in order to be effective in
- 19 a -- in a research project like this, one needs a
- 20 collaborative team, and Dr. Samet represented the
- 21 epidemiologic and medical expertise that we relied on

- 22 as we had to make decisions about the statistical
- 23 modeling.
- 24 Q. Did Dr. Samet discuss with you possible
- 25 confounders?

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- 1 A. Yes. We -- we had numerous conversations about
- 2 that and other issues in epidemiology, other
- 3 epidemiologic issues.
- 4 Q. Did Dr. Samet recommend to you any specific
- 5 statistical methods to be used in the model?
- 6 A. No.
- 7 Q. What was Dr. Miller's role?
- 8 A. Well Dr. Miller is a health economist, and --
- 9 and he has considerable expertise in the study of the
- 10 health effects of smoking. He's the author of the
- 11 United States government's Center for Disease
- 12 Control, that's the CDC, Study on Smoking and Health
- 13 Expenditures, and so he -- his expertise was from an
- 14 economics, health economics perspective. He also,
- 15 along with Dr. Wyant, did some of the -- most of the
- 16 computing in the project.
- 17 Q. What was Dr. Wyant's role?
- 18 A. Well Dr. Wyant is a Ph.D. biostatistician with
- 19 considerable expertise in using complex data sets,
- 20 big, large data sets and putting them together in
- 21 order to be able to effectively address a question
- 22 like this one. So he -- he took responsibility for
- 23 the data sets and for much of the computing in the --
- $24\,$ $\,$ in the project. He's also an expert biostatistician
- 25 with experience in -- in claims cases like this from STIREWALT & ASSOCIATES
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- 1 previous experience in cases like this.
- 2 Q. And what was your role, Professor Zeger?
- 3 A. My role was, again, as a collaborator with the
- other three, helping make decisions about the direction for the project. I worked on all aspects
- 6 and focused quite considerably on what we have called
- 7 the core model which we'll talk about.
- 8 I also, I would say, had responsibility for --
- 9 because of my background in the application of
- 10 statistical methods to public health, for ensuring
- 11 that we were using appropriate statistical methods
- 12 when we did the model.
- 13 Q. Are we going to talk about the core model in a
- 14 moment?
- 15 A. Yes.
- 16 Q. Doctor, how long have you worked --
- Professor, how long have you worked on this project?
- 19 A. I think it's been about 18 months. My
- 20 participation has been about 18 months.
- 21 Q. Have you attended meetings?
- 22 A. Yes. Many, many meetings, hundreds of --
- 23 perhaps a hundred meetings.
- 24 Q. Have you had discussions with Drs. Samet, Miller
- 25 and Wyant regarding this model?

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- Yes. Ongoing, extensive discussions.
- Is this an example of the type of collaborative
- effort that you have previously testified about? 3
- A. Yes. This has gone exactly the way other
- 5 collaborations I have described go with different
- expertise brought to the table where we worked 6
- 7 together on trying to solve a problem.
- 8 Q. In developing plaintiffs' statistical model, did
- you follow commonly practiced biostatistical 9
- principles? 10
- A. Yes. 11
- And can you tell us what those are. 12 Q.
- 13 A. Well the first one is already illustrated on the
- board. The first principle which we followed was to 14
- 15 try to start with a foundation in health, not to
- work, you know, in a vacuum as statisticians, but
- 17 rather to work with an understanding of what the
- 18 health process is by which there might be additional
- expenditures. And Dr. Samet really provided that to 19
- us, and it's drawn there on the board. It's what --2.0
- 21 The reason there might be additional
- expenditures is because smoking causes disease, and 22
- 23 it's the disease that causes money -- it causes us to
- 24 have additional expenditures or results in additional
- 25 expenditures.

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- Ο. What other biostatistical principles did you
- follow?
- Well, having a framework like this, we then 3
- would ask what's the best available information in
- order to look at -- at how smoking causes disease 5
- which results in expenditures, and we went out and 6
- identified the best possible information to do this 7
- 8 project. And in this case, the thing right in the
- 9 middle of those three steps is disease, and what we 10
- were able to do was to go and actually get some 280 million doctors' bills records. Basically, these are 11
- 12 claims records from the state and from Blue Cross
- 13 Blue Shield, and these records have on them the
- 14 diseases that Minnesotans had over the period of time
- 15 we were studying, as well as the dollars expended to
- 16 treat those diseases, as well as some other
- 17 information about the people. And so -- and -- and
- I -- and that was an enormous, you know, effort, but 18
- 19 also very valuable information in order to be able to
- 20 look at what the health -- what -- what the
- 21 smoking-attributable expenditures were.
- 22 Q. You used the term "claim record." What do you
- 23
- 24 A. My understanding of the claim record is that
- 25 when -- when a doctor files a bill to be paid for the STIREWALT & ASSOCIATES
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- state or for Blue Cross Blue Shield, you know,
- there -- there's a record kept of the bill with the

- 3 information that I described, and these 280 million
- 4 records are largely listings of every claim that was
- 5 made by a doctor or by another provider for services
- 6 rendered.
- 7 Q. And are these records kept by the state of
- 8 Minnesota?
- 9 A. Yes.
- 10 Q. And are these records kept by -- or are there
- 11 different records kept by Blue Cross Blue Shield of
- 12 Minnesota?
- 13 A. Yes. Both the state and their programs, the
- 14 Medicaid program and in the General Assistance
- 15 Medical Care program, both of those are programs for
- 16 people who are poor, to provide medical care for
- 17 people who are poor, they -- they keep detailed
- 18 records of every expenditure that they made and --
- $19\,$ $\,$ and what the disease was and what treatment was
- 20 provided, the dates and so forth. And Blue Cross
- 21 Blue Shield does the same thing.
- 22 Q. And did the claims records at Blue Cross Blue
- 23 Shield cover any particular plans?
- 24 A. Yes. Blue Cross Blue Shield has what are called
- 25 group plans where if you work for a company and the STIREWALT & ASSOCIATES
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- 1 company wants to be insured, medically insured with
- 2 Blue Cross Blue Shield, they would cover all the
- 3 employees of the company, and so it was for those
- 4 kinds of plans that we had information.
- 5 Q. So these were the claims records that were
- 6 collected.
- 7 A. Yes.
- 8 Q. Now can you tell us essentially what's on a
- 9 claim record?
- 10 A. Yes. A claims record has a date of certain --
- 11 it has a person I.D., a name. We didn't get the
- 12 names. But it had a person I.D., an
- 13 identification -- an identifier for a person, it has
- 14 what service was rendered, what disease the service
- 15 was for, what's called an international -- an IDC-9
- 16 code -- ICD-9 code, international classification of
- 17 Disease code, which is basically indicating what sort
- 18 of treatment it was for what sort of disease it was.
- 19 And then the kind of service that was provided and
- 20 then the dollars expended. And it also has some
- 21 information about the person, it has their -- their
- 22 age and their gender, and in some cases it has some
- 23 more information about them, marital status, I think,
- is an example.
- 25 Q. Do the claims records include any information STIREWALT & ASSOCIATES
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- 1 about smoking?
- 2 A. No.
- 3 O. And that's true for the state of Minnesota?
- 4 A. Yes.
- 5 Q. It's also true for Blue Cross Blue Shield?
- 6 A. There's no smoking information on the medical
- 7 claims records.

- 8 Q. Did we obtain smoking information about
- 9 Minnesotans?
- 10 A. Yes, we did.
- 11 Q. Where?
- 12 A. So -- so the first data set we got was the 280
- 13 million claims records. There's another data set
- 14 called the Behavioral Risk Factor Surveillance
- 15 System, or BRFSS, B-R-F-S-S, Behavioral Risk Factor
- 16 Surveillance System.
- 17 Q. Could you tell us about that --
- 18 A. Yes.
- 19 Q. -- survey.
- 20 A. This is a -- an ongoing survey that's run by the
- 21 Department of Health for the state, and it's actually
- 22 a survey that's done by many states coordinated --
- 23 coordinated by the federal Centers for Disease
- 24 Control. And this is a survey of health behaviors,
- 25 and so it has information, for example, about whether STIREWALT & ASSOCIATES
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- 1 people smoke or not, and then much -- considerable
- 2 other pieces of information about the person's health
- 3 behaviors. So we were able to get over an 11-year
- 4 period, I think it was, 1984 to 1994, some 35,000
- 5 records on citizens of Minnesota indicating
- 6 information about their health behaviors, in
- 7 particular their smoking, whether they smoked or not.
- 8 Q. Did we obtain information from any other surveys
- 9 or sources of data?
- 10 A. Yes. There was one other large source which I
- 11 want to mention now which was in order -- which we
- 12 needed in order to understand the relationship
- 13 between smoking and disease, so there's -- there's a
- 14 study called the National Medical Expenditure Survey,
- or NMES, NMES, the National Medical Expenditure
- 16 Survey.
- 17 Q. Can you tell us about that survey.
- 18 A. Yes. This is a survey that is done every 10
- 19 years by the federal government, the last one was
- 20 done in 1987, and they're going to be -- I think
- 21 they're starting one soon. There's one in the field
- 22 now. And this is a study that's done -- survey
- 23 that's done in order to identify factors which
- 24 influence expenditures on health care. So we -- we
- 25 were able to obtain data from the National Medical STIREWALT & ASSOCIATES
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- 1 Expenditure Survey, the one in 1987, originally
- through a sample of some, I think, 28,000 people
- 3 around the country, and we -- we have used that data
- 4 as well.
- 5 Q. And what kinds of information is on -- is in
- 6 that data?
- 7 A. Right. Well the National Medical Expenditures
- 8 Survey is the one place where we actually have
- 9 information about all the steps in our medical
- 10 foundation. We have information about whether people
- 11 smoke or not, we -- we have information about what
- 12 diseases they have, and we have information about how

```
many dollars were spent to treat their diseases.
13
    Q. Professor Zeger, did you use any other
14
    principles of biostatistics in preparing the
15
```

16 statistical model in this case?

A. Yes, we did. So the first principle we -- we 17

18 used was to start with a medical model, smoking

causes disease which results in expenditures, then we 19

went out and found -- with that model we went out and 20

found the best data for expenditures, disease and 21

smoking. And -- and -- and we found considerable 22

amounts of -- of data for each of those. 23

24 Then the next question is: How should we 25 organize the estimation of the smoking-attributable STIREWALT & ASSOCIATES

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expenditures? How should we go about trying to 1 estimate those dollars? And so --

3 Q. With the court's permission, could you come down and show us on the flip chart how you went about organizing those dollars.

Okay. Thank you. 6

4

5

7

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So we basically broke the problem up into some parts that we could -- each of which we could manage more directly, and the way we broke it up really was dictated by this medical underpinning to our approach given to us by Dr. Samet. And there are dollars expended for all kinds of things, and what we did is we classified those dollars by what I'll call disease or conditions.

So let's just start -- what we first did is we broke the problem into looking at the expenditures for medical services, medical services, and -- and I'm distinguishing medical services from the other kind of services, which were in order to maintain people in nursing homes. The state spends money for persons who are -- are poor and go into nursing homes, and these fees are not to provide medical care to them in the nursing homes, but only to pay their residence fees. So we decided, given smoking causes disease which -- which results in dollars, to treat STIREWALT & ASSOCIATES

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1 the -- the medical expenditures separately from expenditures for maintaining people in nursing homes. 3 Okav?

4 And then if we look at the medical expenditures, we further broke that into two pieces. Okay? There -- there are two kinds of medical expenditures, 6 and again it keys off of Dr. Samet's model. We -- we 7 8 focus on the diseases, and we broke it into a part 9 that had to do with the major smoking-attributable diseases, and to another group of diseases or

10

conditions which Dr. Samet has called diminished 11

health. And then we further broke up the major 12

13 diseases into two groups, lung cancer and chronic

14 obstructive pulmonary disease, or COPD. And then

15 all -- all of the remaining, there are 10 others that

16 were identified by Dr. Samet, and since the most

17 common ones are coronary heart disease and stroke,

- 18 we'll call that group CHD/stroke, but I'll put a
- 19 little plus there to indicate that there are other
- 20 conditions as well in that group.
- 21 Q. Professor Zeger, let me stop you there. Could
- 22 we have on the Elmo Trial Exhibit 30153, which has
- 23 been previously admitted into evidence, Your Honor,
- 24 and could you identify for us what that exhibit is?
- 25 A. Yes. This is a listing of the ICD-9 codes, the STIREWALT & ASSOCIATES
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- 1 International Classification of Diseases, 9th
- 2 Revision for ICD-9, and these numbers here, 440-441,
- 3 444 and so forth, those are the ICD-9 codes, and
- 4 these were identified by Dr. Samet. It's basically a
- 5 listing of the diseases which we call the major
- 6 smoking-attributable diseases. And also it's listed
- 7 here diminished health at the bottom, which is not
- 8 one of what we call the major smoking-attributable
- 9 diseases.
- 10 Q. Now was this list of diseases provided to you by
- 11 Dr. Samet?
- 12 A. Yes.
- 13 Q. Did you have any involvement in the preparation
- 14 of this list?
- 15 A. No
- 16 Q. Now could you tell us which diseases are in the
- 17 first portion of major smoking-attributable diseases
- 18 marked lung cancer, COPD, using the ICD-9 code list?
- 19 A. Let's see if I can find it. Here's lung cancer.
- 20 Q. Right.
- 21 A. ICD-9 code 162. And chronic obstructive
- 22 pulmonary disease is right here, COPD, and there's a
- 23 couple of codes for that one.
- 24 Q. And could you identify for us the diseases in
- 25 the CHD/stroke category of the model.

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- 1 A. Yes. It's all the other major diseases
- 2 identified by Dr. Samet, so let me just quickly go
- 3 through them. Atherosclerosis, bladder cancer,
- 4 cerebrovascular disease, coronary heart disease,
- 5 esophageal cancer, kidney cancer, laryngeal cancer,
- 6 oral cancer, pancreatic cancer, and peptic ulcer
- 7 disease. Those are the ones that we're calling
- 8 CHD/stroke -- the CHD/stroke group.
- 9 Q. Thank you.
- 10 A. And then just -- just to make this point, this
- 11 diminished health is the last entry, this is not a
- 12 major smoking -- not a major smoking-attributable
- 13 disease, but it's the last category that we've --
- 14 we've divided the problem into.
- 15 Q. Professor Zeger, did you use any other
- 16 biostatistical principles in developing the
- 17 plaintiffs' model in this case?
- 18 A. Yes, there was one other I want to mention,
- 19 which is, as with any large problem, we have -- we
- 20 have a medical foundation, we went out and found the
- 21 best data, and we've tried to break the problem into
- 22 sensible parts that we could attack. But the other

- 23 thing that's useful to do is to try to not only go at
- 24 sort of the whole big solution, but, you know -- or
- 25 the complex solution, but to also build sort of a $$\tt STIREWALT\ \&\ ASSOCIATES$
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- 1 simple model, one that's easy to understand, one
- 2 that's easy to explain, and -- and so I would call
- 3 the principle of trying to take a simple approach as
- 4 well as a refined approach to estimating
- 5 smoking-attributable expenditures, and that's what
- 6 we've done.
- 7 Q. What did you call the simple approach?
- 8 A. I've called it the core model. The core model.
- 9 And I called it core model because our purpose was in
- 10 trying to build some simpler calculations. These --
- 11 these don't have all the bells and whistles on them,
- 12 but they're the core, they're the heart of what
- 13 happens in the refined model. So we have this
- 14 refined model and a core model which is simpler, but
- 15 we purposefully designed the core model to allow
- 16 us -- allow us as the statisticians and medical
- 17 scientists to understand what -- what's going on at
- 18 the core of the calculation, how the calculations are
- 19 actually being made, so that we would have confidence
- 20 that the refined model was doing the right thing.
- 21 And it also has the very valuable purpose, so that
- 22 you can explain it to other people. So that when we
- 23 look at what the core model does, that's exactly
- 24 what's happening in the full refined model, but --
- 25 but the core model has been designed so you can STIREWALT & ASSOCIATES
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- 1 explain it clearly and you can see what's going on
- 2 clearly so you'll understand what's happening in the
- 3 refined model better. And I must say that the goal
- 4 is for us to understand ourselves first, and then to
- 5 be able to explain it to other people accurately.
- 6 Q. Now you worked on both the core and the refined 7 models?
- 8 A. Yes, I did.
- 9 Q. Have you followed this principle in your work
- 10 apart from this case?
- 11 A. Yes.
- 12 Q. I mean is --
- 13 A. I try in most of my projects, especially if they
- 14 become complex, to try to look at what's at the heart
- of what's going on in the complex work by creating
- 16 sort of a simple version of it to see that -- how
- 17 these things fit together.
- 18 Q. What diseases did you examine in the core model?
- 19 A. The core model only looks at the major
- 20 smoking-attributable diseases. So in the core model
- 21 we looked at lung cancer, COPD, and we looked at the
- 22 CHD/stroke group, which includes all of the other
- 23 major smoking-attributable diseases.
- 24 Q. Did you address in the core model diminished
- 25 health?

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- 1 A. No.
- 2 Q. Did you address in the -- in the core model
- 3 nursing home residence fees?
- 4 A. No.
- 5 Q. Why did you focus on the major
- 6 smoking-attributable diseases?
- 7 A. I thought that would be the group of diseases
- 8 where it would be easiest to see what was going on
- 9 with our modeling effort where -- where the core
- 10 model would be most valuable.
- 11 Q. Can we turn now to how the core model works.
- 12 How do you identify people with major
- 13 smoking-attributable diseases?
- 14 A. Well we're very fortunate that we have these
- 15 medical claims records. So as I said, we have some
- 16 280 million records, and on each record that is
- 17 describing a doctor's visit, for example, there is an
- 18 ICD-9 code of what -- what was done -- what -- what
- 19 the visit was about. So you can see the codes up
- 20 there again. And what we basically did is we
- 21 searched all of the records, these millions of
- 22 records, to identify Minnesotans who were suffering
- 23 from one of those major smoking-attributable
- 24 diseases, and we uncovered more than 90,000 people in
- $\,$ 25 $\,$ the period of time for which we had the records.

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- 1 Q. What did you do next?
- 2 A. So we had all of the medical records for these
- 3 90,000 people from Minnesota who had these diseases
- 4 caused by smoking, and the next step, then, was to go
- 5 through and for each of the persons find all of their
- 6 expenditures so that we would know in a given year
- 7 how many dollars were expended on a particular person
- 8 who had lung -- lung cancer, for example, or chronic
- 9 obstructive pulmonary disease.
- 10 Q. And did you total all these lung cancer dollars?
- 11 A. Yes. We were able to then total all the dollars
- 12 for medical services provided to all the Minnesotans
- 13 who had lung cancer, for example.
- 14 Q. Is that the smoking-attributable expenditure?
- 15 A. No, that's -- that's not it. That's the total
- 16 dollars that were -- was expended for their
- 17 treatment, not the dollars that were attributable to
- 18 their smoking.
- 19 Q. And what did you do next?
- 20 A. Well what we did is we built a system for taking
- 21 these total dollars, which again come from the
- 22 medical claims data, these are the real dollars
- 23 expended for the real citizens of Minnesota who had
- 24 these diseases that Dr. Samet had indicated were
- 25 caused by smoking. And again, I just want to make STIREWALT & ASSOCIATES
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- 1 the point that it's using his -- his model, smoking
- 2 causes the diseases. We're targeting in on the
- 3 diseases he identified for us.

We totaled up the expenditures for these people 5 and then we applied a series of reductions, because we don't want to take all the dollars expended for 6 7 them as being the ones that are attributable to their smoking, we only want to take a certain part of those 8 9 expenditures. Q. And have you prepared an exhibit showing those 10 11 three reductions? 12 A. Yes, I have. Can you turn to Trial Exhibit 30197. Can you 13 Ο. 14 identify that, please. A. Yes. This is the display that I've created called the core statistical model, three reductions. 16 17 MR. HAMLIN: Your Honor, plaintiffs offer 18 Trial Exhibit 30197 for illustrative purposes. 19 MR. GARNICK: No objection. 20 THE COURT: Court will receive 30197 for 21 illustrative purposes. 22 BY MR. HAMLIN: 23 Q. Professor Zeger, I'm going to put the exhibit up 24 on the easel, and with the court's permission, I'd ask you to come down and could you tell us what is on 25 STIREWALT & ASSOCIATES P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1953 DIRECT EXAMINATION - SCOTT L. ZEGER 5044 this exhibit. 1 A. So let me -- let me just review where we were. 2. We've got all these billing claims records, Minnesota 3 4 claims records. We go through, we find all the 5 people, more than 90,000, who are suffering from lung cancer, COPD, and the other major 6 smoking-attributable diseases identified by Dr. 7 Samet. For each of those people we sum up the total dollars expended by the state or Blue Cross Blue 9 Shield to take care of them. Okay? And that's where 10 we start at the top of this chart. We have the total 11 dollars that was expended on a person who had -- we 12 knew they had a major smoking-attributable disease. 13 14 So that's our starting place. 15 And then what we do is we take those dollars and 16 we reduce those dollars three times. And what I want 17 to do is give an overview, first, of why it is we 18 make these reductions. 19 The total dollars expended for these people, 20 those dollars weren't all caused by their smoking. This is the total dollars expended. There may be 21 dollars in there for things having nothing to do with their smoking. So we have to reduce these dollars. 23 And here's how we do it. The first reduction, 24 25 which we call what percentage are smokers -- now I've STIREWALT & ASSOCIATES P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1953 DIRECT EXAMINATION - SCOTT L. ZEGER already told you the claims data doesn't include 1 information about whether somebody smokes. It's not available. So we have some 90,000 people who we know have diseases that are caused by smoking, but we 5 don't know whether that person in particular is a smoker. So what we do is we get information from 6

another source, the National Medical Expenditure Survey, and we determine the percentage of persons

9 who have that disease. Let's take lung cancer for example. We take -- we -- we determine the fraction 10 11 of persons who have lung cancer who are smokers. 12 Okay? So we have this pool of dollars that's been expended to treat people with lung cancer. We know 13 14 lung cancer causes -- is caused by smoking, so what we do is we reduce the total dollars by the fraction 15 of persons who are smokers. We only take the dollars 16 for the persons -- for the fraction of people who 17 smoke, for the -- for the percentage of people who 18 smoke. And in making that first reduction, what 19 20 we're basically doing is setting aside dollars that have been expended for persons who aren't smokers. 2.1 22 Okay? So that's the first reduction, what percentage 23 are smokers. 2.4 Then we -- what we end up with at the end of the 25 first reduction is the total dollars expended for STIREWALT & ASSOCIATES P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1953 DIRECT EXAMINATION - SCOTT L. ZEGER persons who have lung cancer who are smokers. Okay? And we have an estimate of that. 3 Now we're going to reduce it a second time. Why 4 would we -- why would we reduce it a second time? 5 Because we recognize that some proportion of people who are smokers who end up with lung cancer, they 6 might have gotten lung cancer even if they hadn't 7 been a smoker. In the case of lung cancer, nearly 8 9 all lung cancer cases, people are smokers, but it is 10 possible to get lung cancer if you're not a smoker. 11 You've heard that. So what we want to do is set aside those dollars that -- that -- for people who 12 have lung cancer and who -- and who smoke, but where 13 we think that a fraction of them wouldn't have --14 15 would -- would have had lung cancer even if they hadn't smoked. So that's the second reduction, what 16 percentage of smokers' disease is attributable to 17 18 smoking. 19 Now what we end up with at the end of the second 20 reduction is a pool of dollars that is for smokers 21 whose lung cancer -- or whose disease was caused by their smoking. We've set aside the non-smokers, 22 23 we've set aside the dollars for diseases that would 2.4 have occurred anyway even if the person hadn't 25 smoked, and now we still have one more reduction to STIREWALT & ASSOCIATES P.O. BOX 18188, MINNEAPOLIS, MN 55418 1-800-553-1953 DIRECT EXAMINATION - SCOTT L. ZEGER 5047 go. And that's because at this point we still have dollars in the pool for treatment of conditions which 2 aren't related to the smoking. I mean, you know, if 3 you have lung cancer, you might also have other things happen to you; you might fall down and break your leg and it might have nothing to do with the 6 7 lung cancer. So at this point we still have the total 8 dollars. The third reduction says what dollar 9 10 percentage is attributable to the particular smoking-caused disease? So we want to set aside 11 12 things that aren't attributable to that disease. 13 So what we do is we start at the top of the

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14 chart with the total dollars expended to treat
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- 15 Minnesotans who have diseases that are caused by
- 16 smoking, and we reduce it three times to -- to
- 17 eliminate the non-smokers, to eliminate the disease
- 18 that would have occurred even if the persons hadn't
- 19 been smokers, and then finally eliminate the
- 20 expenditures for services that were unrelated to the
- 21 particular disease we're looking at. And what we get
- 22 at the end of these three reductions, we start with
- 23 total dollars, and what we get at the end is what
- 24 we're calling smoking-attributable dollars.
- 25 Q. Now can you give us an example of how these STIREWALT & ASSOCIATES
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- $1\,$ $\,$ reductions work, and specifically, have you prepared
- 2 a board?
- 3 A. Yes, I've prepared one board for each of these
- 4 reductions.
- 5 Q. All right. Now let me -- let me show you the
- 6 board first. I want to show you Trial Exhibit 30198.
- 7 And was this board prepared at your direction?
- 8 A. Yes, it was.
- 9 Q. And is this a hypothetical example for ten
- 10 thousand Minnesotans?
- 11 A. Yes, it is.
- MR. HAMLIN: Your Honor, plaintiffs offer
- 13 Trial Exhibit 30198 for illustrative purposes.
- MR. GARNICK: No objection.
- THE COURT: Court will receive 30198 for
- 16 illustrative purposes.
- 17 BY MR. HAMLIN:
- 18 Q. Professor Zeger, we'll put the board on the
- 19 easel, and if we could have the previous exhibit up
- 20 on the Elmo.
- 21 Can you tell us what Trial Exhibit 30198 is.
- 22 A. Well what I've done is I've created a
- 23 hypothetical population of people, ten thousand
- 24 Minnesotans, in order for us to actually go through
- 25 what the calculations are to see if they're

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- 1 reasonable. And this is the idea of core model, to
- 2 help us understand that what we're doing is sensible.
- 3 So this is a hypothetical example of ten thousand
- 4 Minnesotans. Okay? And what we've done is we've
- 5 made what -- what I previously called a two-by-two
- 6 table, two rows and two columns, and then a total.
- 7 We won't count that one. So we have ten thousand
- 8 people indicated here, and what this table shows is
- 9 that five thousand of the ten thousand are smokers.
- 10 Okay? And another five thousand are never smokers.
- Now when I use the word "smokers," I'm going to
- 12 include people who are currently smokers, currently
- smoking, and people who are former smokers as well.
- 14 So I'm distinguishing ever smoker from never smoker.
- 15 Okay?
- 16 So I have five thousand smokers and five
- 17 thousand never smokers in my hypothetical population
- 18 of ten thousand people. Okay? Now what else do

- we -- what other information do we have in this table
- in this model? We have whether the person has lung 20
- cancer or not. Okay? So if we looked at the 21
- 22 smokers, there are 5,000 smokers, how many have lung
- cancer? 140. Okay? And how many don't have lung 23
- cancer? Well the remainder, 4,860 don't have lung 24
- 25 cancer.

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- Now let's look at the never smokers. Again,
- there are 5,000 of them in total. How many of them 2. have lung cancer? Twenty of them. Okay? And how 3
- many don't have lung cancer? The remainder. Okay?
- 5 And how many lung cancers are there in total? Well
- there's 140 lung cancers among the smokers and 20 6
- 7 lung cancers among the people who didn't smoke, so
- there's a total of 160 people who have lung cancer in
- 9 this hypothetical population. Okay?
- Q. And then could you go on with the example. 10
- A. Yes. So what we now want to do is we want to 11
- look at the first reduction. The first reduction 12
- 13 says we only want to take money for the percentage of
- people who are smokers. You see what we get in 14
- 15 our -- from our claims records is we identify these
- 160 people, we search all the claims and we're able 16
- to find out that 160 people have lung cancer. Okay? 17
- 18 But we don't know -- we don't know whether they're a
- 19 smoker or not from the Minnesota claims data. Okay?
- 20 So what do we -- what do we need to do to take this
- 160? Do we want to take -- make -- make all the 21
- dollars expended for them and say that's due to 22
- smoking? No, that wouldn't be fair to do that. 23
- 24 Okay? Do we want -- do -- is it fair to get the
- 25 money for these never smokers, these 20 never

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- smokers? No. Smoking clearly didn't cause their disease. 2.
- Okay. So the first reduction says of the 160 3
- 4 people who have lung cancer, what percentage of them
- 5 are smokers? Okay? Well we have the information we
- need here. We see 140 people are smokers out of a 6
- total of 160. So that's how we do the first 7
- 8 reduction. And we can actually look at that.
- 9 Ο. Do you --
- 10 Have you prepared a board showing the
- 11 calculation for the first reduction?
- A. Yes, I have. 12
- All right. And --13 Q.
- 14 A. If we put it up there, I think it will be
- 15 helpful.
- 16 Q. Actually, I think -- why don't you go back and
- 17 identify it first and then we'll put it up.
- 18 I want you to turn to Trial Exhibit 30191.
- 19 A. Yes.
- 20 Q. Is that the board or the exhibit that you
- 21 prepared showing the first reduction calculation?
- 22 A. Yes, it is.
- MR. HAMLIN: Your Honor, plaintiffs offer 23

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Trial Exhibit 30191 for illustrative purposes.
25
              MR. GARNICK: No objection.
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               THE COURT: Court will receive 30191 for
 1
    illustrative purposes.
    Ο.
        You've got the exhibit now on the Elmo. Could
 3
    you explain that.
 4
 5
    A. Yes. So just to recap, we -- we started with
    all the dollars, with 160 people who had lung cancer,
 6
 7
    and now we're trying to work our way towards the
    percentage of dollars which you could attribute to
 8
9
    their smoking.
         Well clearly you can't attribute to smoking the
10
11 dollars spent for people who didn't smoke. All
12
    right? So what we need to know is the fraction of
13
    dollars, the percentage of dollars that was for
14
    smokers. Okay? Well here we have the information in
15
    the table we need, and this was the standard practice
    in statistical analyses, we see that of the people
16
17
    who have lung cancer, the 160 people, 140 of them are
18
    smokers and 20 were not. So how do we reduce the 160
19
    down to 140? Because we shouldn't take money for
20
    these 20 persons. You simply calculate a percentage
21 which is 140 out of 160, or 87.5 percent. And that's
22 what we call the first reduction percentage. And if
23
   you take 87.5 percent of 160 people, you get 140
24
    people. Okay?
25
         So at the end of the first reduction, what we've
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    done is we've taken all of the people with lung
 1
     cancer and we've estimated the fraction -- estimated
     the -- the number that -- that are smokers. Okay.
 3
    We start with 160, we multiply 160 by the first
 4
 5
    reduction percentage, 87.5, and we end up with just
    the smokers, 140.
 6
 7
        Go ahead and go back.
   Ο.
              MR. HAMLIN: Your Honor, this may be a good
 8
9
    time to break.
10
              THE COURT: All right. We'll recess,
11
    reconvene tomorrow morning at 9:30.
12
             (Recess taken.)
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